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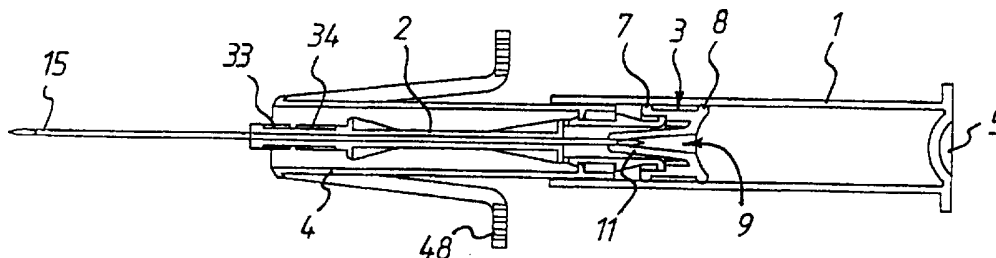
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(54) Title: SAFETY SYRINGE



(57) Abstract

A safety syringe has a barrel (1), a piston with a piston body (2) and a piston head (3), and a protective sheath (4) which carries piston engaging formations. A fluid pathway extends through the head (3) and body (2) and the body (2) is locatable to extend within the sheath (4) and be engaged by the piston engaging formations, with the head (3) outside the sheath (4) and connected to and in fluid communication with the body (2). The barrel (1) is slidable over the head (3) and sheath (4) in a discharge position to release the piston engaging formations and grip the released piston, the barrel (1) being slidable from the discharge position to withdraw the released piston substantially from the sheath to a safe locked position relative to the sheath.

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SAFETY SYRINGE

FIELD OF THE INVENTION

This invention relates to a safety syringe.

BACKGROUND TO THE INVENTION

With the increasing risk of infection through needle injuries, there is a demand for a syringe which can be used and disposed of in a manner which reduces the risk of such injury.

OBJECT OF THE INVENTION

5 It is an object of this invention to provide a safety syringe.

SUMMARY OF THE INVENTION

In accordance with this invention there is provided a syringe comprising :
a generally tubular protective sheath carrying piston engaging formations and having a needle end and an opposite rear end;

10 a piston including an elongate piston body and a piston head, there being a fluid pathway through the head and longitudinally through the body, the piston body being operatively locatable to extend within the sheath and be engaged by the piston engaging formations, with the piston head outside the sheath and connected to and in fluid communication with the piston body;

15 a barrel which is slidable in a discharge stroke in use over the operatively located piston head and the sheath to a discharged position, to thereby release the piston engaging formations, and grip the released piston, the barrel being oppositely slidable from the discharged position to withdraw the released piston substantially from the sheath to a safe locked position relative to the sheath.

20 Preferably in a first embodiment of the invention the piston body has a front and a rear end, with front and rear piston clips thereon, and the sheath has stops at its

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5 rear end, the piston clips and stops being arranged to enable the piston body to be inserted into the sheath with the rear clips engaging the sheath stops and locking the piston body against withdrawal from and insertion into the sheath, in that rotational orientation with the sheath, and being further arranged to enable movement of the barrel to its discharged position to release the rear piston clips, and to enable the front piston clips to engage the stops on movement of the piston body to the safe locked position.

10 There is provided for the sheath to have a first and second axial keyway means, the first keyway means having a cross sectional shape designed to guide a clip rotating therein in use into the second keyway means, and the second keyway means having abrupt edges designed to prevent rotational movement of a clip therein in use.

15 Further, each of the first and second keyway means are a pair of diametrically opposed matching keyways, with the pairs located at 90 degrees to each other in cross-sectional orientation of the sheath.

Each keyway of a pair has a transverse clip stop, the clip stop of the first keyway pair being located further into the sheath interior than the clip stop of the second keyway pair.

20 Preferably, the front piston clips of the piston body form keyway slides, and have opposed clipping formations, being a front formation which is able to slide over the stops in a forward direction only, and a rear formation which is able to slide over the stops in a withdrawal direction only.

25 The rear clips of the piston body may have opposed clipping formations, being a forward clipping formation slidable over stops on insertion into the sheath, and a rear formation which abuts the stops when the piston body is slid into the sheath.

Preferably, the rear formation of the rear piston clips is shaped to co-operate with the piston head, on movement of the piston head with the barrel at the end of a discharge stroke in use, to disengage the forward formation of the rear piston clip from its stop.

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Alternatively, the piston engaging formations on the sheath may include barbed flaps arranged to engage slots on the piston.

Preferably, these flaps are part of the sheath wall and project axially rearwardly from a hinged end at the needle end of the sheath, having free ends engagable by the barrel end at the end of a discharge stroke to hinge the flaps outwardly and out of engagement with the slots.

Further, the slots are carried in diametrically opposed piston catches which extend axially from the piston body at a front end thereof, and are resiliently inwardly deformable.

The sheath may have the same keyway configuration. To this end the sheath may have a first and second axial keyway means, the first keyway means having a cross sectional shape designed to guide a clip rotating therein in use into the second keyway means, and the second keyway means having abrupt edges designed to prevent rotational movement of a clip therein in use, each keyway means having a transverse stop at the rear end of the sheath, and in which the catches form keyway slides, arranged to enable insertion of the piston body into the first keyway means with the catch slots engaged in the first keyway means stop, and to enable rotation of the piston body in this location to guide the catches into the second keyway means, free of the second keyway means stop in an insertion direction of the piston body into the sheath, and further to enable the withdrawal of the piston body with the catches in the second keyway means to a position where the catch slots engage the stop at the second keyway means to lock the piston body against insertion and withdrawal.

There is also provided for the piston head to be integral with the piston body.

A further feature of the invention provides for the piston to be separate from the piston body and to be connectable to the piston body to form the piston.

BRIEF DESCRIPTION OF THE DRAWING

Embodiments of the invention are described below by way of example only, and with reference to the accompanying drawings, in which:

Figure 1 is a sectioned longitudinal side view of a barrel and piston head according to the invention;

Figure 2 is a sectioned longitudinal side view of a piston body and a sheath according to the invention;

Figure 3 is a sectioned longitudinal side view as for Figure 2, but rotated through 90 degrees around the sheath and piston body axis;

Figure 4 is a partially cut away isometric view of the piston head connected to the piston body, and inserted in the sheath;

Figure 5 is an isometric view of the rear end of the piston body;

Figure 6 is an isometric view of the front end of the piston body;

Figure 7 is an isometric view of the rear entrance to the sheath;

Figure 8 is an isometric view of two longitudinal halves of the rear end of the sheath cut away and opened for explanatory purposes;

Figure 9 is a view of the front of the piston body inserted in the sheath in a packaged position;

Figure 10 is a sectioned longitudinal side view of the piston body and sheath after a relative one quarter turn of the piston body within the sheath from the packaged position;

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Figure 11 is an isometric view of the configuration of the embodiment in Figure 10;

Figure 12 is a side view of the piston body fully inserted within the sheath in an armed position.

5 **Figure 13** is a partly sectioned isometric view of the rear of the piston body in the position of Figure 12;

Figure 14 is a view of the assembled syringe with barrel and piston head connected to the sheath and piston body in a loaded condition;

10 **Figure 15** is a side view of the syringe shown in Figure 14 after a discharge stroke;

Figure 16 is a longitudinal side view of the syringe with the barrel in a fully depressed unlocked position;

Figure 17 is a longitudinal side view of the barrel of the syringe with the barrel withdrawn to a safe position;

15 **Figure 18** is a part sectioned isometric view of the front of the piston body clipped into the rear of the sheath with the syringe in the safe position, as shown in Figure 17;

Figure 19 is a longitudinal side view and cross-section of a barrel of an alternative embodiment of the invention;

20 **Figure 20** is a longitudinal cross-section of a piston body and integral piston head of the alternative embodiment;

Figure 21 is a sectioned longitudinal view of a sheath of the alternative embodiment;

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Figure 22 is a partly sectioned isometric view of the inter-action between the front end of a piston body, the sheath and a piston barrel in the alternative embodiment;

Figure 23 is an isometric view of the configuration of Figure 22 showing the releasing action of the flaps.

DETAILED DESCRIPTION OF THE DRAWINGS
WITH REFERENCE TO THE DRAWINGS

Referring to Figures 1 to 3, a drug delivery system is in the form of a syringe having a barrel (1), a piston with an elongate piston body (2), and a piston head (3), and a sheath (4).

The barrel is tubular with a closed rear end (5) and an open front or needle end (6), and is preferably made of glass. A stopper may alternatively be provided to close the rear end, enabling the use of a simple length of glass tube for the barrel.

Referring to Figures 1 and 4, the piston head (3) is of elastomeric material and is reciprocable within the barrel. It has integral front and rear sealing rings (7) and (8) therearound at each axial end, and a blind axial passageway (9) extending into a rear axial end (10) within a conical projection (11). The projection extends past the front sealing ring (7) where the projection end (12) forms an integral plug to the blind end of the passageway.

The front sealing ring carries an annular radially inwardly extending lip (13) opposed recesses (13a) are provided to allow a twist-clip action when the piston is operatively located.

The piston body (21) (Figures 2, 3 and 6) has a central hypodermic needle (14) running in its length, extending from a front or needle end (15) to just short of, and within, an opposite rear end (16).

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The rear end (16) is shown in more detail in Figures 4 and 5. It is tubular, open at the rear, and surrounds the rear needle in (17) as it extends into the interior of the tubular space (18).

5 On diametrically opposed sides of the tubular rear end are hinged rear piston clips (20) and (21). The clips lie within the tubular wall, and extend axially from hinges at their rear ends, to be resiliently pivotable into and out of the tubular space (18). Each clip has two spaced apart outwardly projecting ramp catches, with one catch (23) at its free end and one ramp (24) at its hinged end. The slopes (25) of the ramp catches face away from each other, and the ledges (26) 10 oppose each other.

Positioned at 90 degrees to the clips (20) and (21), on the outside of the rear end of the piston body, are diametrically opposed lateral stops (30).

On the outside of the rear edge are diametrically opposed lugs (27) arranged to co-operate with recesses (13a) of the piston head.

15 The front end of the piston body is shown in more detail in Figure 6. Diametrically opposed pairs of barbed clipping formations (32) extend outwardly from the piston body. Each pair (32) has one clip (33) extending from the body acutely and axially towards the rear of the piston body, and one clip (34) similarly extending towards the front of the body in the same plane as its mate, in the form 20 of opposed barbs. The ends of the clips of a pair stop short of each other with a gap (35) between them.

Referring to Figures 2, 3, 7 and 8, the sheath (4) is shown. It has a rear end (38) and a front or needle end (39). The entrance to the rear end, (Figures 7 and 8) is divided into four quarters by two pairs or matching axial keyways. Each keyway 25 of one pair (40) is bound at its axial sides by edges which extend inwardly and towards each other in the manner of a dovetail slot. These keyways have transverse stops (41) which run from edge (42) to edge (42) at the height of the edges, just inwardly of the rear end. Apart from these stops, the keyways run the length of the sheath uninterrupted, and are referred to as the "long" keyways.

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5 The other pair of keyways (44), have no abrupt edges. Each keyway extends smoothly in cross-section, from and at the height of, the axial edges (42) to a central depth equal to the depth of the long keyways. The second keyways each have a transverse stop (45) extending arcuately across them at the height of the edges (42). The stops (45) are spaced inwardly of the stops (41) from the rear end of the piston body. The smooth cross-sectional shape of the second pair of keyways provide a cam action in use, and these keyways are referred to as the "cam" keyways.

10 The sheath has two finger grips (48) set diametrically opposite each other, and extending from the front end (39) of the sheath outwardly.

15 In use, the syringe is provided in a packaged condition as illustrated in Figures 1 to 3. This position is achieved by preloading the barrel (1) with a required fluid, and inserting the piston head (3) therein to act as a stopper. Suitable covering or other sealing may be provided for the purposes of maintaining sterility. The piston body (2) is inserted into the sheath at the entrance end thereof. This is done by aligning the piston body to slide the barbs (32) down the cam keyways causing the front barbs (33) to clip over the stop (45) and the rear barbs (34) to lock behind them. The piston body in this rotational orientation, is locked in position. The needle is fully contained within the sheath and is protected.

20 To use the syringe, the piston body is rotated one quarter turn (Figure 10) which causes the both sets of barbs (33) and (34) to be radially depressed by the shape of the camming surface of the cam keyways. As the barbs align with the long keyways at the end of the quarter turn, they clip resiliently outwardly into them.

25 The stops in the keyways are arranged to cause the rear barb (34) to clip outwardly in the keyway passed the stop of the long keyway. This position is shown in Figure 11 in more detail.

30 The piston body may now be slid freely into the sheath with the needle protruding from the front sheath end. As shown in Figure 12, the piston body is slid until the

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front catch (23) of the clips (20) at the rear piston body end clip over the transverse stops of the cam keyway (45).

5 The piston is oriented so that the rear piston clips (25) are at 90 degrees to the front barb catches (32). In this position, the lateral stops (30) of the rear piston end abut the stops (41) of the long keyway, with the rear ramp catch (24) outside the sheath. The piston body is now locked within the sheath against both further insertion, and withdrawal.

10 The barrel and piston head, forming a pre-packaged dosage of particular fluid, is now inserted over the piston head and the sheath. This causes the rear needle end (16) to pierce the end (12) of the projection, and enter the passageway (9), thus causing a complete passageway from the rear end of the piston head, through the needle and the piston body, to the free end of the needle projecting from the sheath. It will be appreciated that at least a piston head portion that reciprocates within the barrel should remain outside the sheath, to avoid the
15 necessity of intermediate seals, and a gripping mechanism to extract the piston. This position is shown in Figure 14.

Further depression of the barrel over the piston, with the finger supported on the finger grips (48), causes a discharge of the fluid in the piston through the piston head and out of the needle. At the fully depressed position the rear end of the
20 barrel abuts the piston head. (Figure 15).

To unlock the piston head and piston body, the barrel is further depressed to cause the front flanges of the piston head (13) to slide further over the rear end of the piston body (24). This is shown in Figure 16, and in detail in Figure 4. With the piston head contained within the barrel, it cannot expand outwardly
25 away from the ramp catches (20) and the piston head lip (13) rides over the slope of ramp catch (24), thus forcing it to hinge inwardly, and displace the ramp catch (23) from its engaged position over the stop (45).

The barrel is now withdrawn from the sheath, taking the piston head and piston with it under force of friction. The barbed clips (33) and (34) slide in the long
30 keyway until they engage at the top in the entrance to the rear end of the sheath.

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As shown in Figure 18, the rear barbed clips (34) clip over the stops (41) of the long keyway, and the barbed clips (33) and (34) engage against the stops (41). The piston body is now locked in position in the long keyways, with the stops (41) engaged in the gap (35) between the barbed clips. It cannot be further withdrawn, nor inserted, and any rotation is arrested by the dovetail edges (42) of the long keyway.

The barrel may be further slid right off the piston body if desired, but the needle is drawn up inside the sheath to be fully contained therein, and safe from any accidental contact.

Referring to Figures 19 to 23 an alternative embodiment is shown. A barrel (51) is substantially similar to the barrel of the first embodiment, of Figures 1 to 18, save that it has a central rod (52) extending down from a rear end (53) passed a front end (54) of the barrel. The front edges of the barrel (55) are chamfered downwardly towards the barrel centre.

A piston (60) (Figure 20) has an integral piston head (61), reciprocable within the barrel, and an elongate body (62) terminating in a needle fitting (63) for receiving a conventional hypodermic needle. Diametrically opposed sets of clips (64) are provided at the front end adjacent the needle fitting (63). An axial passageway (65) passes through the piston from the head to the needle end. The passageway is shaped to receive the barrel rod when the barrel is slid over the piston from the head end.

A sheath (70) has a rear end (71) and the same configuration (72) of keyways as described with reference to the first embodiment. The sheath is tubular having finger grips (73), and differs from the first embodiment in that it has front flaps (74) in the form of barbed flaps, located diametrically opposed to each other.

This embodiment functions substantially similarly to the first embodiment, save that with the integral piston head (61), the clips (64) on the piston body and flaps (74) on the sheath are used to unlock the piston.

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5 The piston body catches (64) are resiliently inwardly movable, and each have a centrally located recess (66) therein. The flaps (74) are part of the wall of the sheath, and are hinged at a front end (75) with a protruding ramp catch (76). The slope of the ramp faces rearwardly, so that with the piston in the barrel, the clip (64) can move down the sheath in an arming motion and engage the clip (74) in the recess (66).

10 The barrel can now be withdrawn leaving the piston behind, secured by the clips (74). This enables fluid to be drawn into the barrel through the needle. The clips (74) are released from under the barrel, and under the biasing of the clips (64), the clips (74) protrude slightly outwardly above the sheath surface. The fluid is discharged by depressing the barrel over the piston. On this discharge stroke the chamfered front end of the barrel flaps the protruding sheath clips (74) and lifts them outwardly out of engagement with the piston clips (64). This position is shown in detail in Figure 23.

15 The piston is now held within the barrel under friction force, and can be withdrawn with the barrel to a safe position within the sheath. The recesses (66) of the clips (64) engage with the transverse stops of the long keyway, locking the piston.

20 In use, the syringe is assembled by inserting the piston, located fully within the barrel, (60) into the sheath (70). This is done by inserting the clips (64) in the cam keyway, rotating them to align them in the long keyways, and sliding the barrel and piston fully into the sheath. The catches (64) bend inwardly to engage with the clips (74), since the barrel rides over the clips (74) and holds them against outward hinging. This is shown in more detail with reference to Figure 22.

CLAIMS

1. A syringe comprising :

a generally tubular protective sheath carrying piston engaging formations and having a needle end and an opposite rear end;

a piston including an elongate piston body and a piston head, there being a fluid pathway through the head and longitudinally through the body, the piston body being operatively locatable to extend within the sheath and be engaged by the piston engaging formations, with the piston head outside the sheath and connected to and in fluid communication with the piston body;

a barrel which is slidable in a discharge stroke in use over the operatively located piston head and the sheath to a discharged position, to thereby release the piston engaging formations, and grip the released piston, the barrel being oppositely slidable from the discharged position to withdraw the released piston substantially from the sheath to a safe locked position relative to the sheath.

2. A syringe as claimed in claim 1, in which the piston body has a front and a rear end, and front and rear piston clips thereon, and the sheath has stops at its rear end, the piston clips and stops being arranged to enable the piston body to be inserted into the sheath with the rear clips engaging the sheath stops and locking the piston body against withdrawal from and insertion into the sheath, in that rotational orientation with the sheath, and being further arranged to enable movement of the barrel to its discharged position to release the rear piston clips, and to enable the front piston clips to engage the stops on movement of the piston body to the safe locked position.

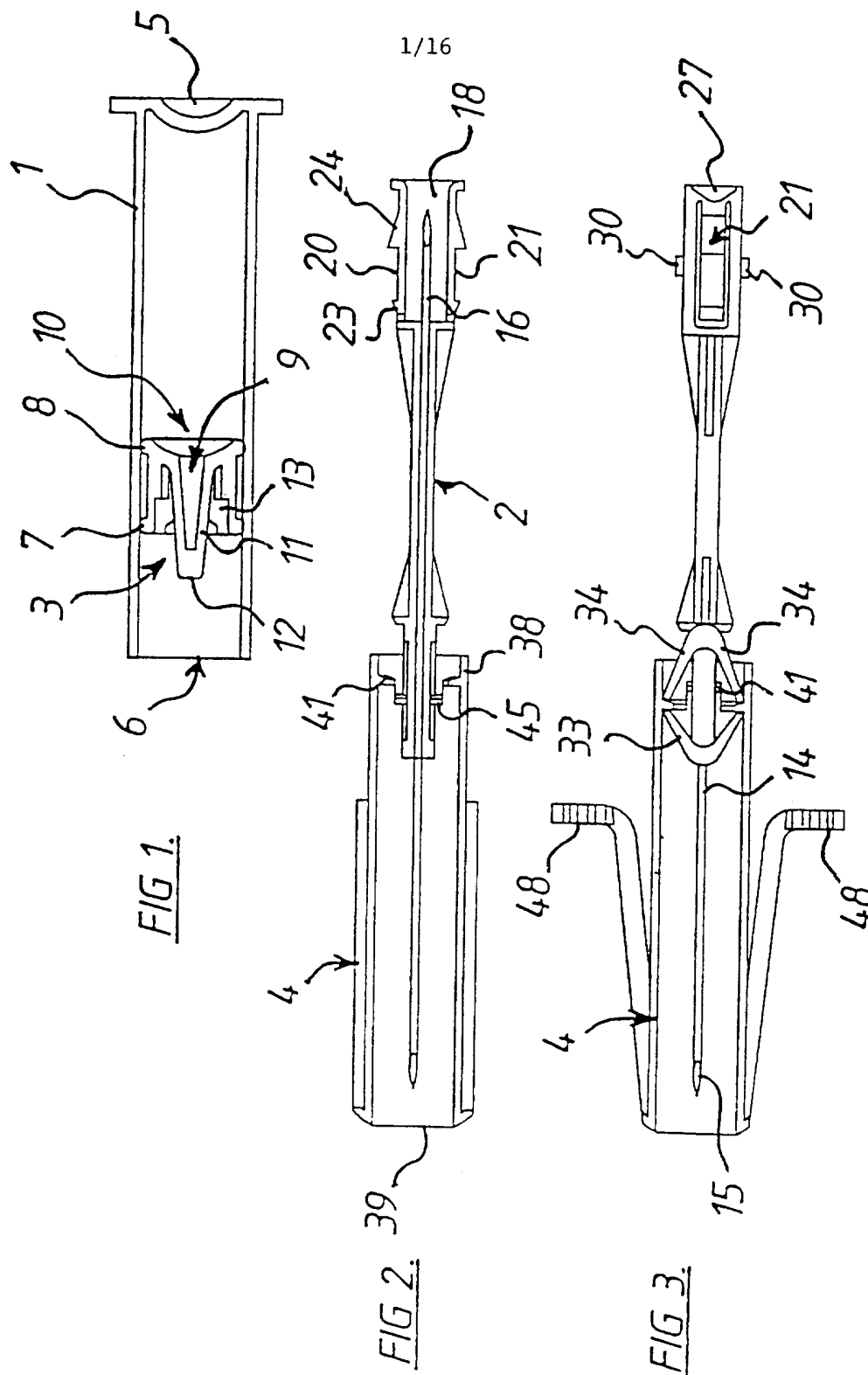
3. A syringe as claimed in claim 2, in which the sheath has a first and second axial keyway means, the first keyway means having a cross sectional shape designed to guide a clip rotating therein in use into the second keyway means, and the second keyway means having abrupt edges designed to prevent rotational movement of a clip therein in use.

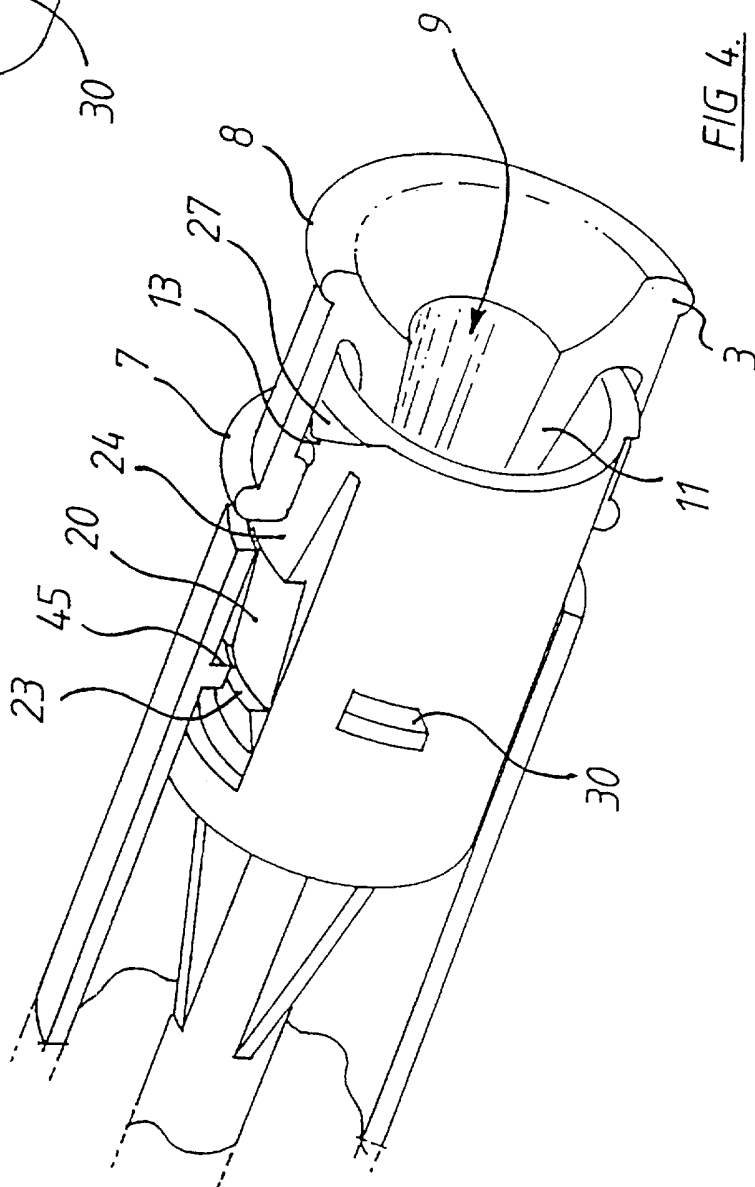
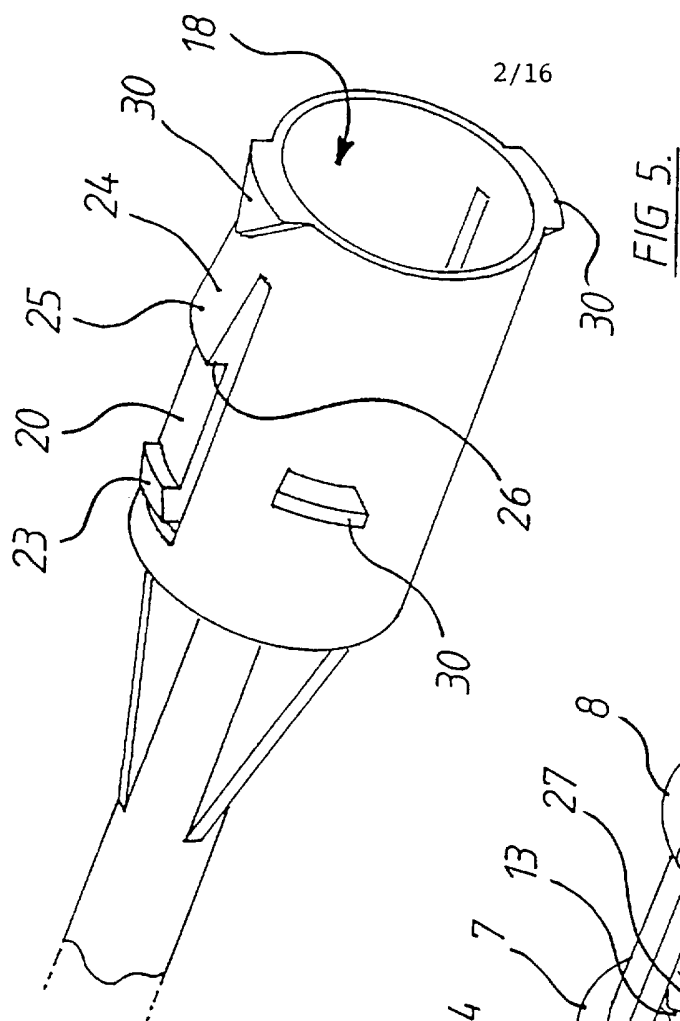
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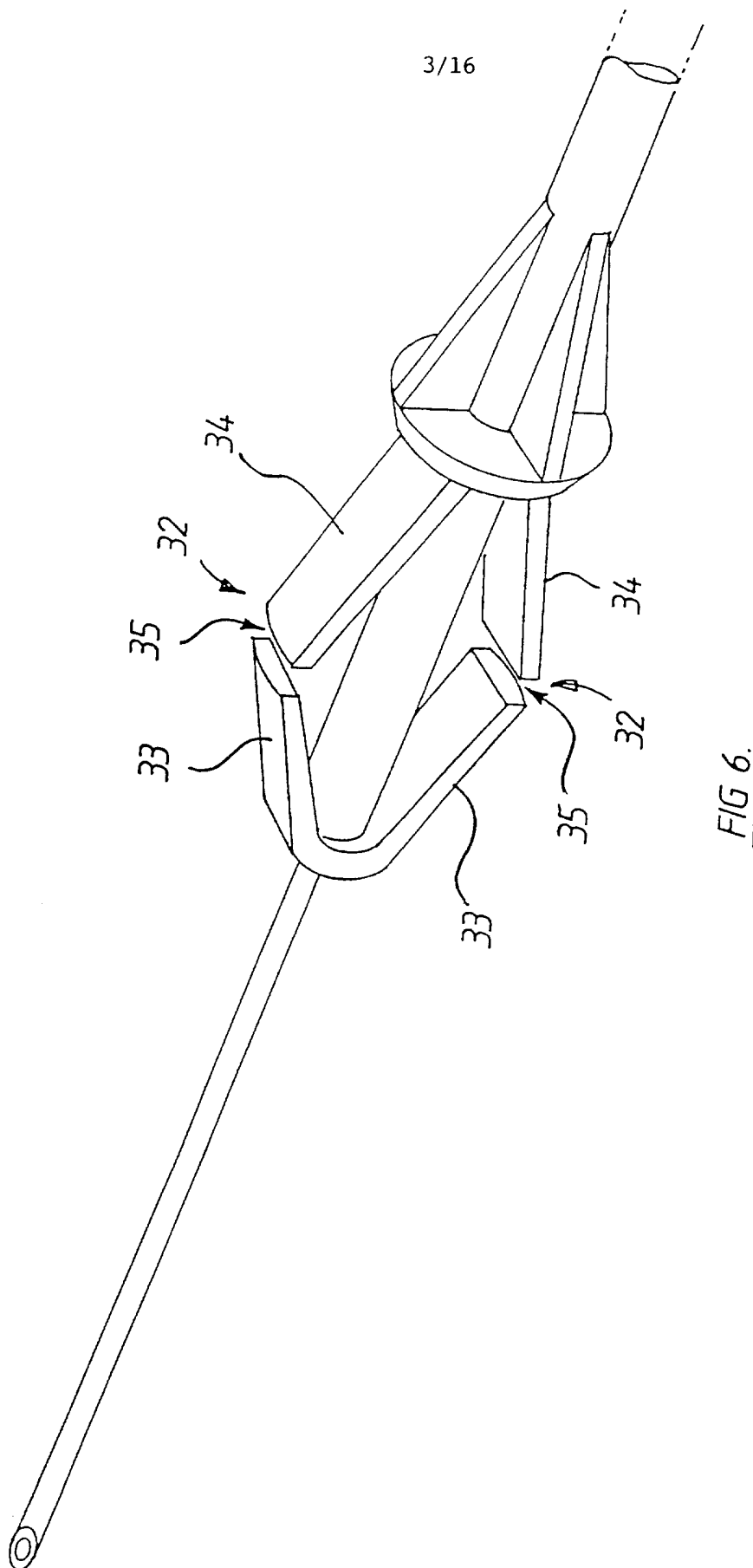
4. A syringe as claimed in claim 3, in which each of the first and second keyway means are a pair of diametrically opposed matching keyways, with the pairs located at 90 degrees to each other in cross-sectional orientation of the sheath.
- 5 5. A syringe as claimed in claim 4, in which each keyway of a pair has a transverse clip stop, the clip stop of the first keyway pair being located further into the sheath interior than the clip stop of the second keyway pair.
6. A syringe as claimed in claim 5, in which the front piston clips of the piston body have form keyway slides, and have opposed clipping formations, being a front formation which is able to slide over the stops in a forward direction only, and a rear formation which is able to slide over the stops in a withdrawal direction only.
- 10 10 6. A syringe as claimed in claim 5, in which the front piston clips of the piston body have form keyway slides, and have opposed clipping formations, being a front formation which is able to slide over the stops in a forward direction only, and a rear formation which is able to slide over the stops in a withdrawal direction only.
7. A syringe as claimed in claim 6, in which the rear clips of the piston body have opposed clipping formations, being a forward clipping formation slidable over stops on insertion into the sheath, and a rear formation which abuts the stops when the piston body is slid into the sheath.
- 15 7. A syringe as claimed in claim 6, in which the rear clips of the piston body have opposed clipping formations, being a forward clipping formation slidable over stops on insertion into the sheath, and a rear formation which abuts the stops when the piston body is slid into the sheath.
8. A syringe as claimed in claim 7, in which the rear formation of the rear piston clips is shaped to co-operate with the piston head, on movement of the piston head with the barrel at the end of a discharge stroke in use, to disengage the forward formation of the rear piston clip from its stop in use.
- 20 8. A syringe as claimed in claim 7, in which the rear formation of the rear piston clips is shaped to co-operate with the piston head, on movement of the piston head with the barrel at the end of a discharge stroke in use, to disengage the forward formation of the rear piston clip from its stop in use.
9. A syringe as claimed in claim 1, in which the piston engaging formations on the sheath include barbed flaps arranged to engage slots on the piston.
10. A syringe as claimed in claim 9, in which the flaps are part of the sheath wall and project axially rearwardly from a hinged end at the needle end of the sheath, having free ends engagable by the barrel end at the end of a discharge stroke to hinge the flaps outwardly and out of engagement with the slots.
- 25 10. A syringe as claimed in claim 9, in which the flaps are part of the sheath wall and project axially rearwardly from a hinged end at the needle end of the sheath, having free ends engagable by the barrel end at the end of a discharge stroke to hinge the flaps outwardly and out of engagement with the slots.

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11. A syringe as claimed in claim 10, in which the slots are carried in diametrically opposed piston catches which extend axially from the piston body at a front end thereof, and are resiliently inwardly deformable.
- 5 12. A syringe as claimed in claim 11, in which the sheath has a first and second axial keyway means, the first keyway means having a cross sectional shape designed to guide a clip rotating therein in use into the second keyway means, and the second keyway means having abrupt edges designed to prevent rotational movement of a clip therein in use, each keyway means having a transverse stop at the rear end of the sheath, and in which the catches form keyway slides, arranged to enable insertion of the piston body into the first keyway means with the catch slots engaged in the first keyway means stop, and to enable rotation of the piston body in this location to guide the catches into the second keyway means, free of the second keyway means stop in an insertion direction of the piston body into the sheath, and further to enable the withdrawal of the piston body with the catches in the second keyway means to a position where the catch slots engage the stop at the second keyway means to lock the piston body against insertion and withdrawal.
- 10 13. A syringe as claimed in any one of the preceding claims, in which the piston head is integral with the piston body.
- 15 20 14. A syringe as claimed in any one of claims 1 to 12, in which the piston is separate from the piston body and is connectable to the piston body to form the piston.







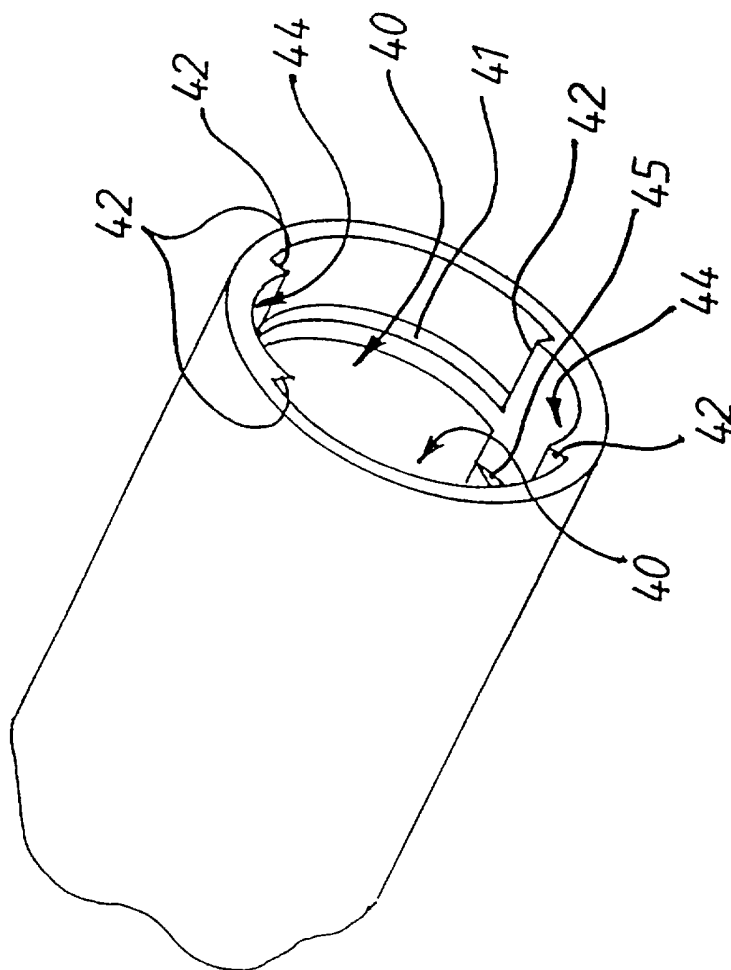


FIG 7.

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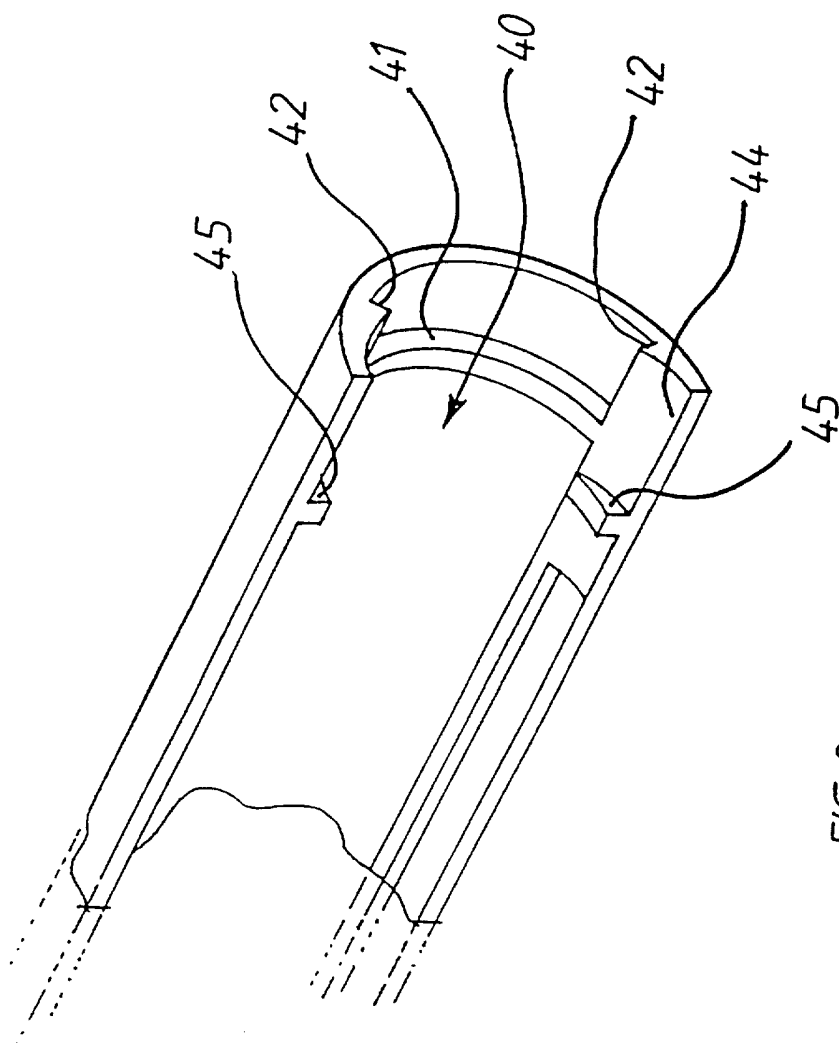


FIG 8.

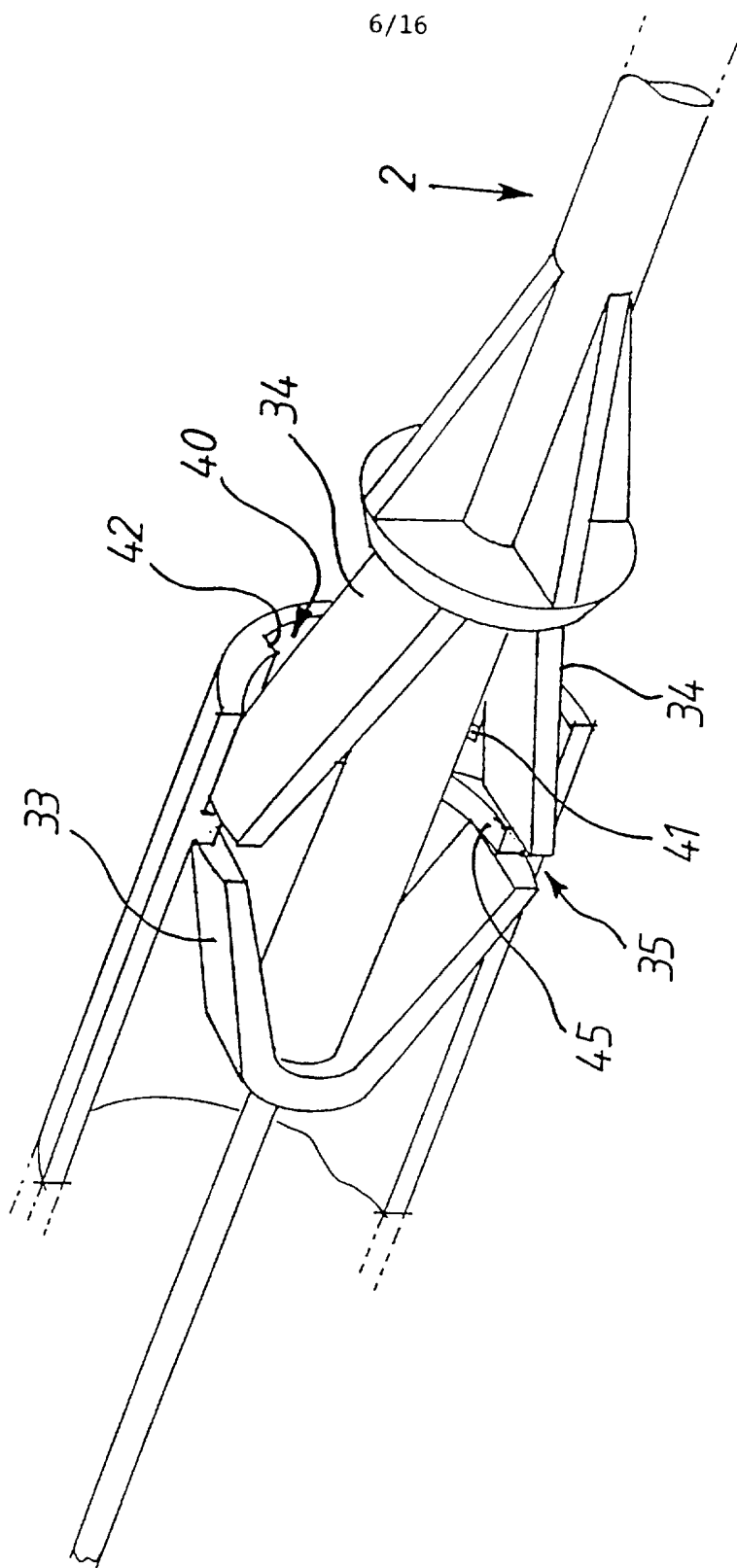


FIG 9.

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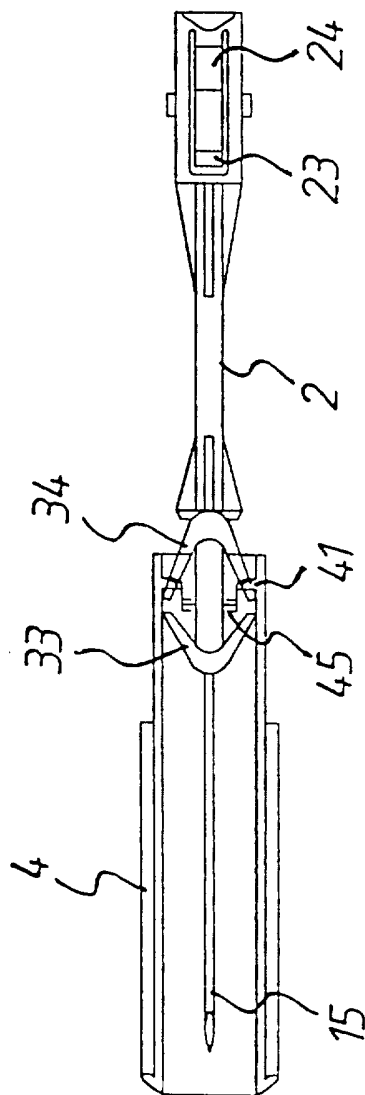


FIG 10.

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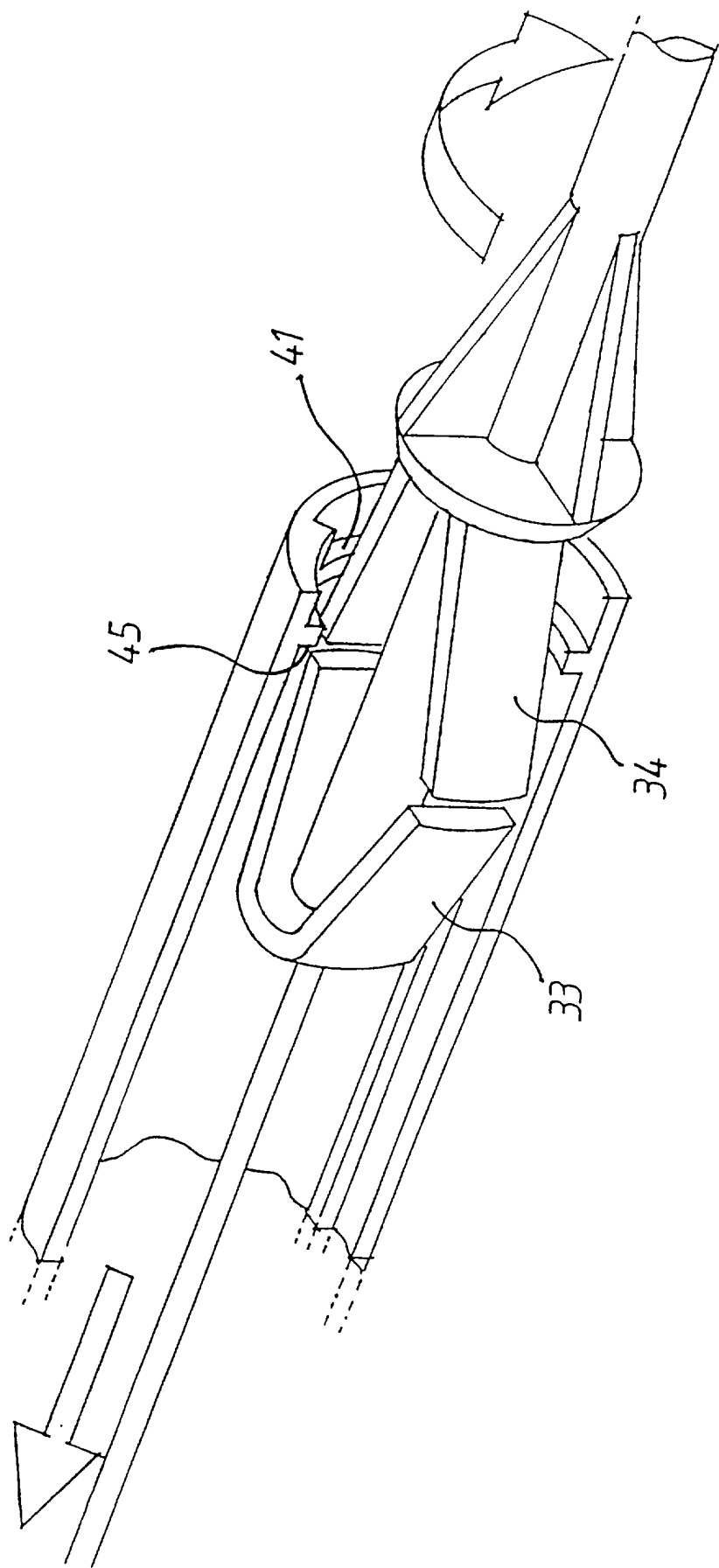


FIG 11.

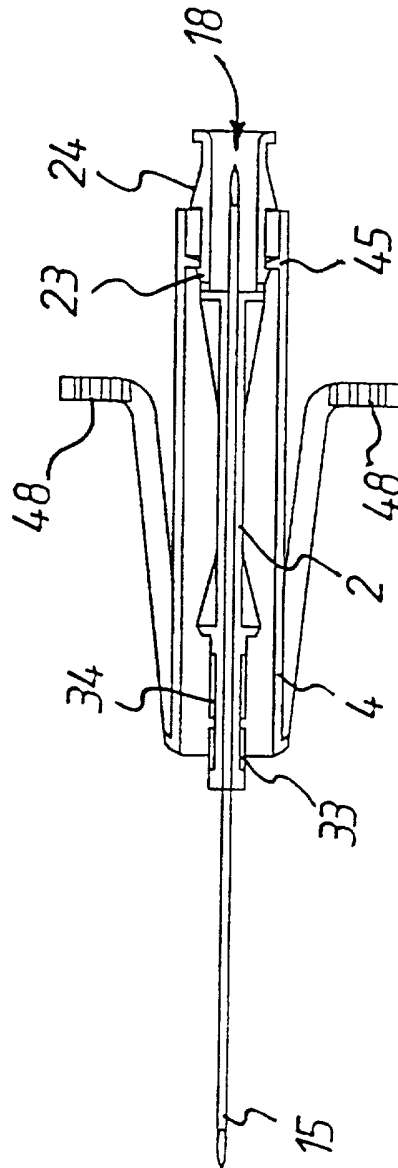
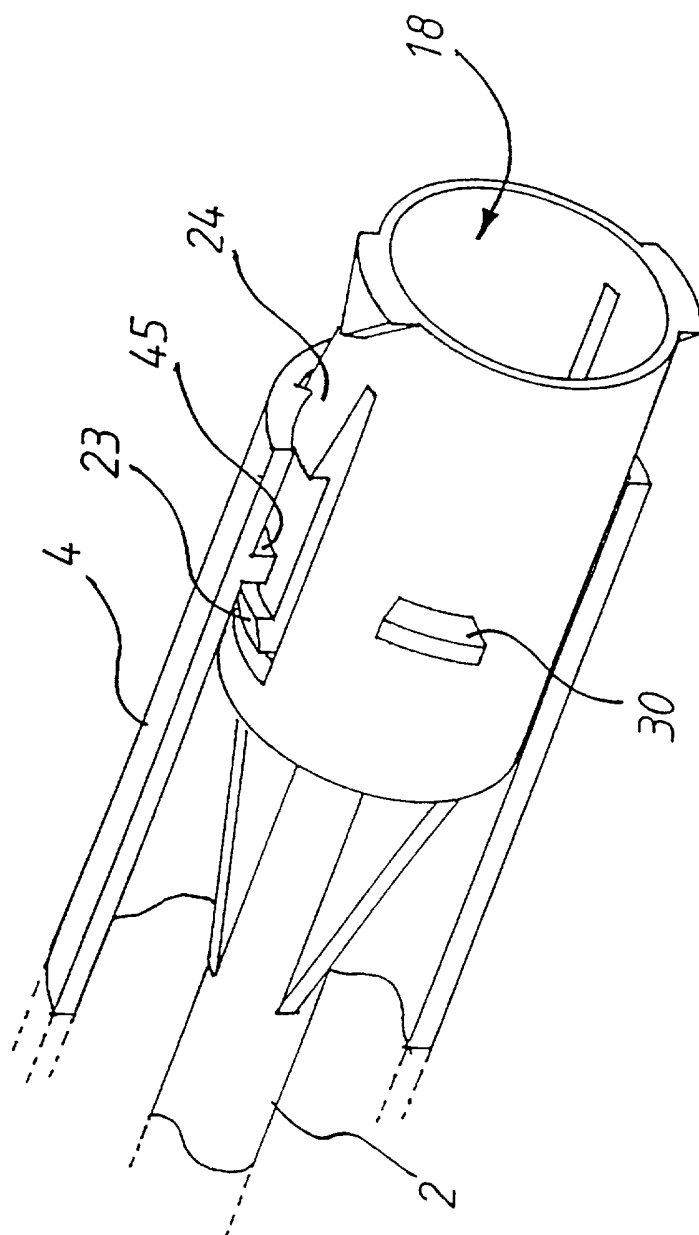
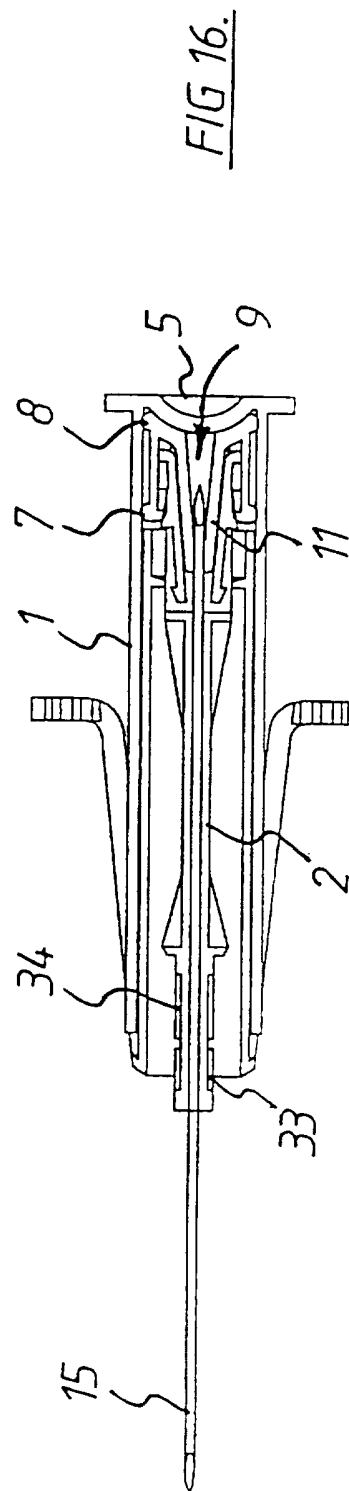
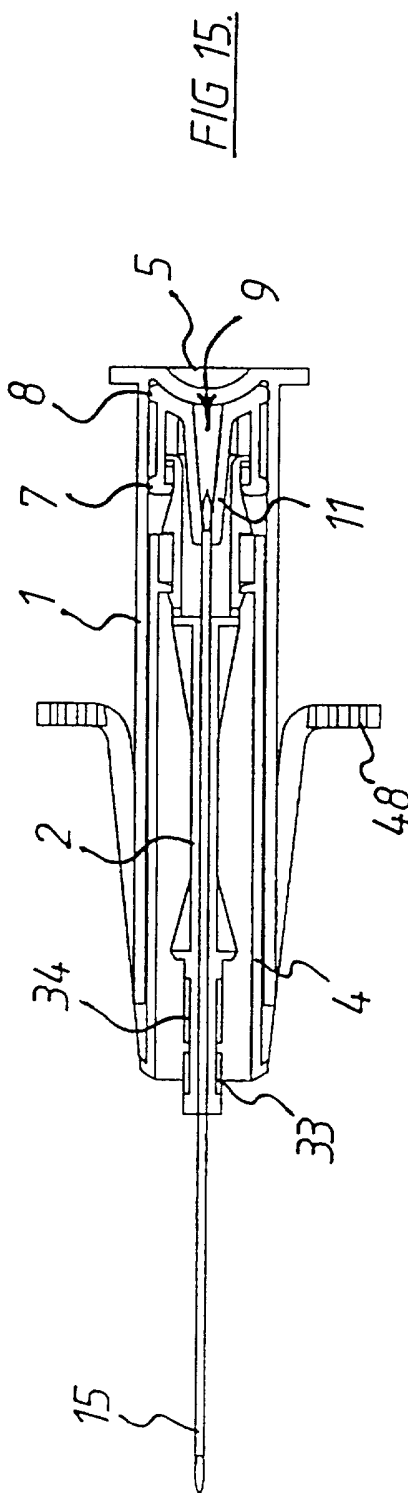
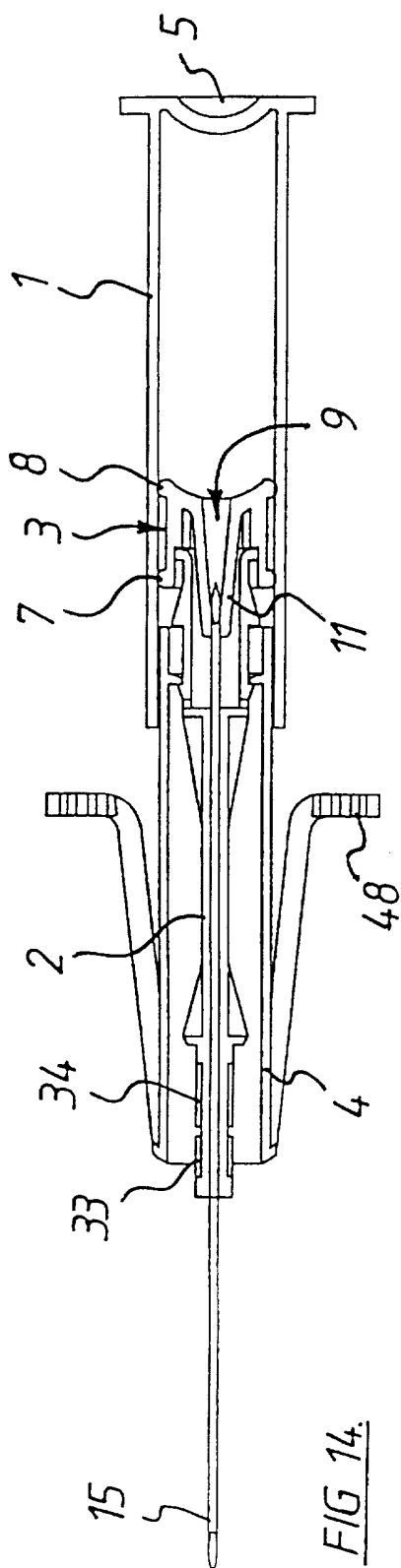


FIG 12.

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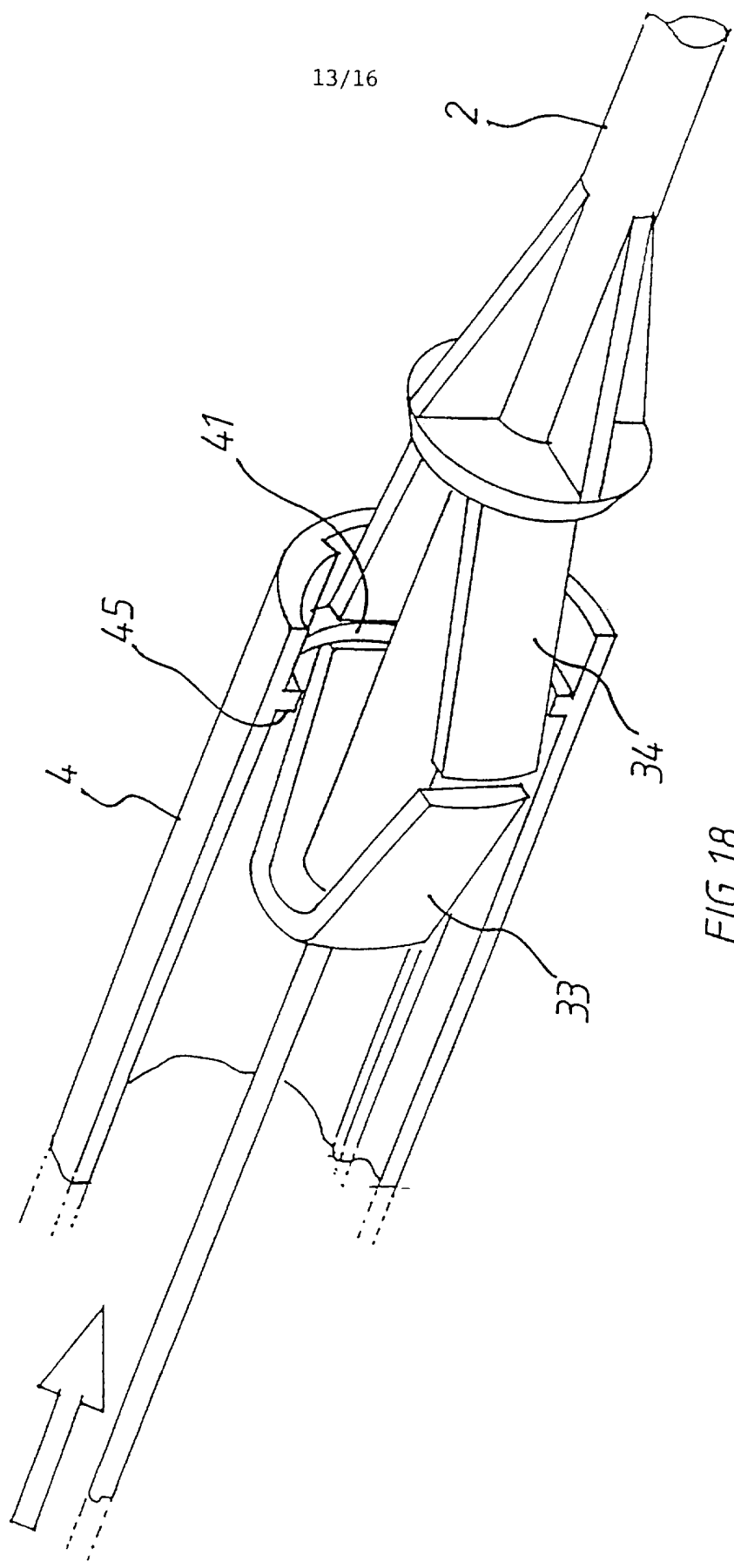


FIG 18

FIG 19.

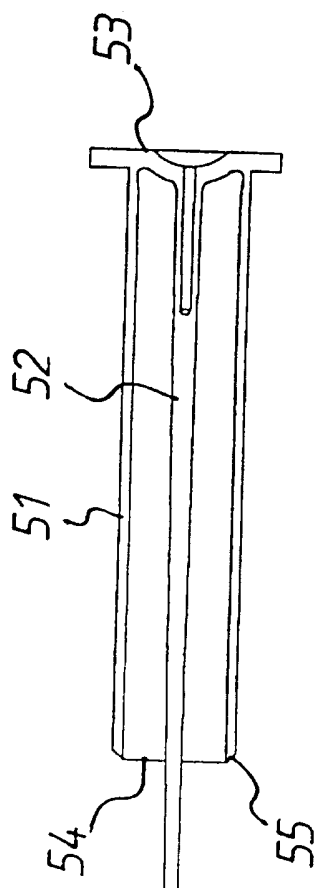


FIG 20.

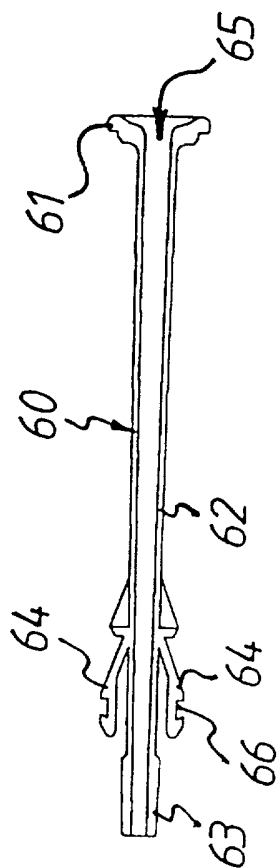
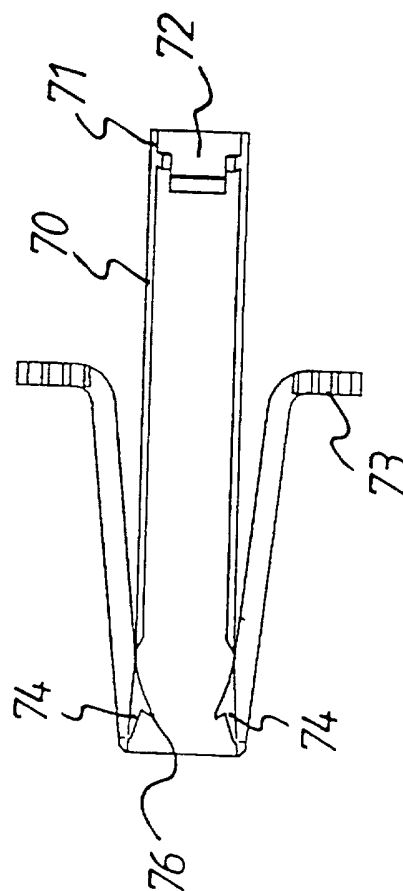


FIG 21.



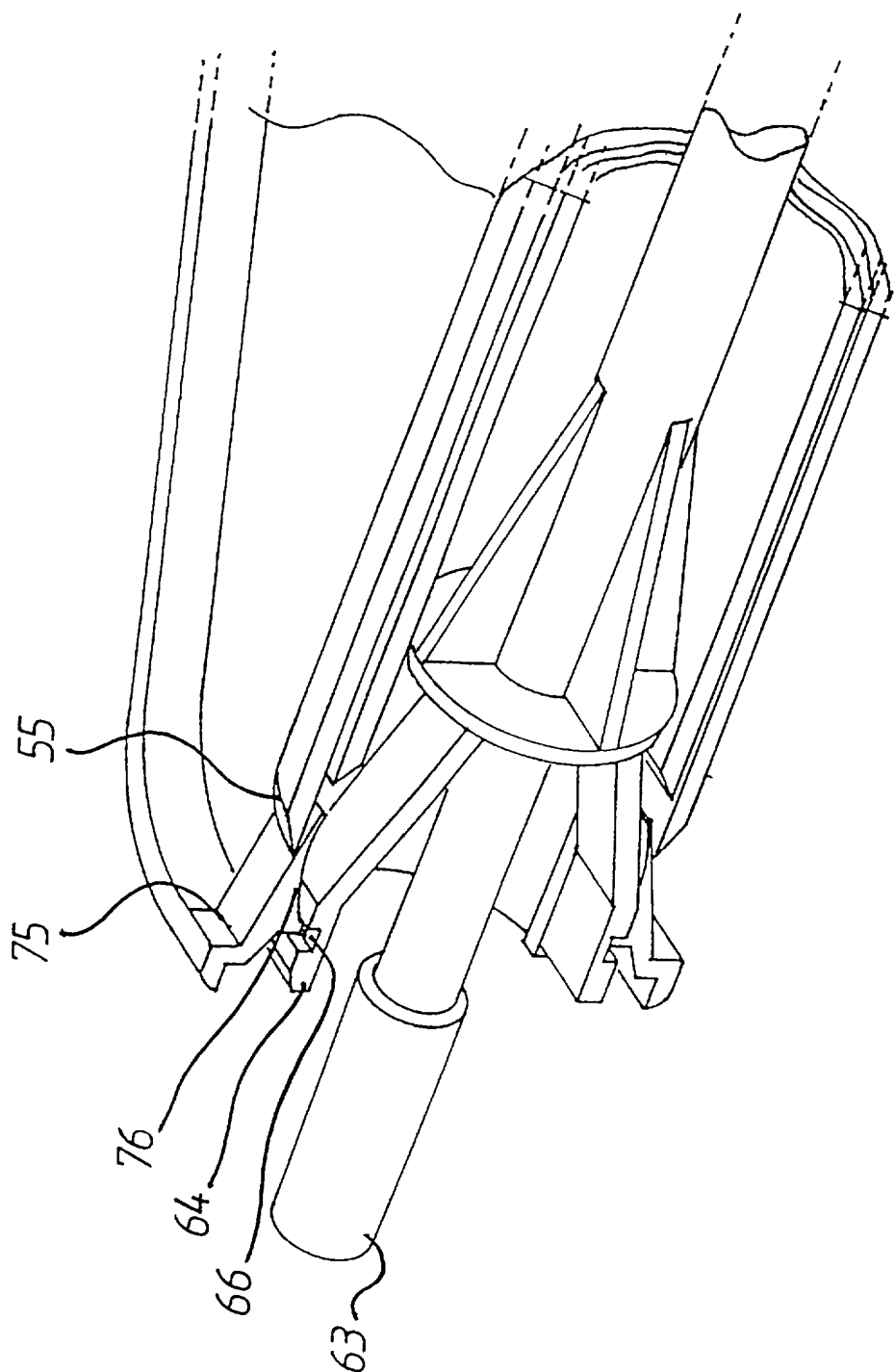


FIG 22.

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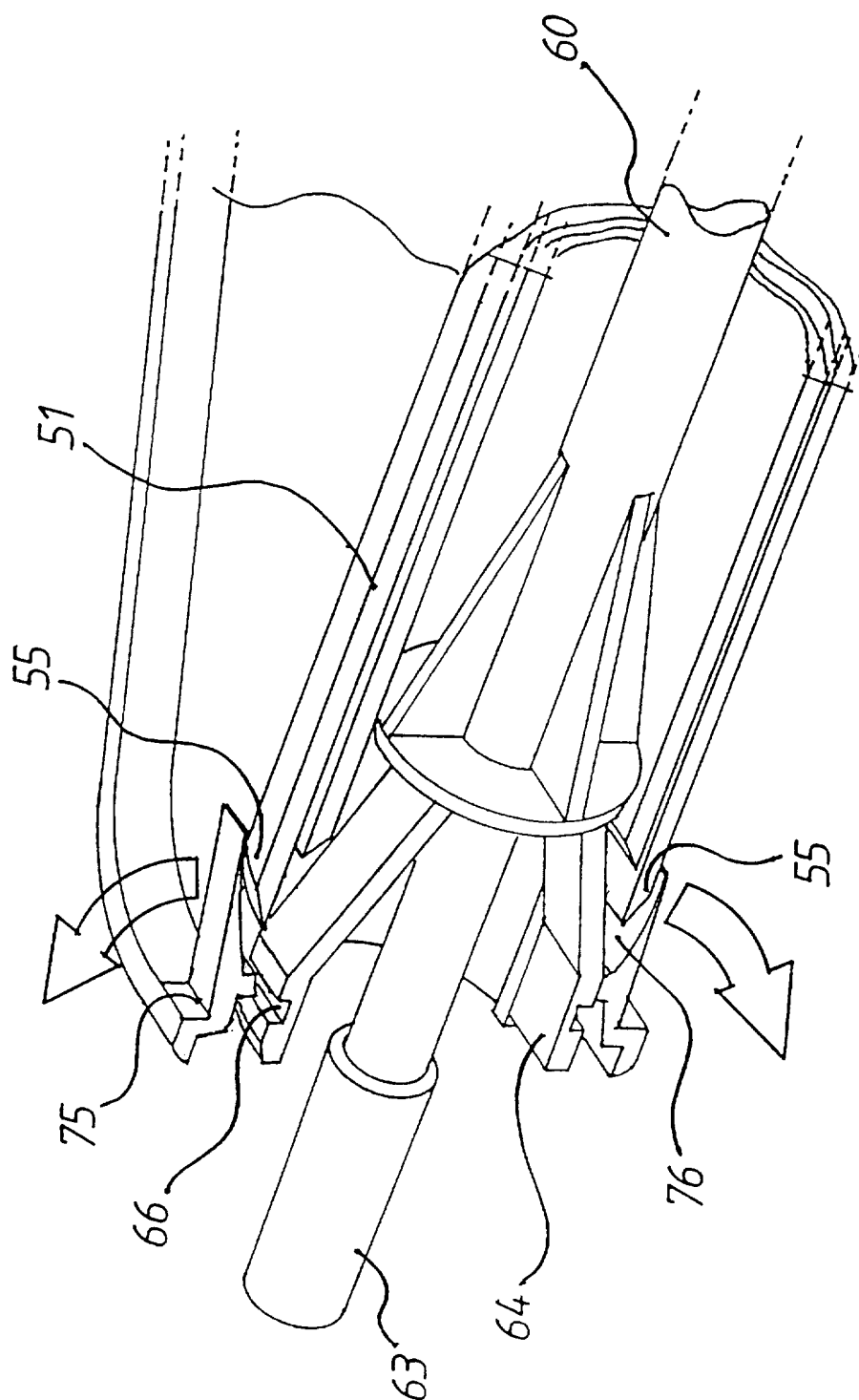


FIG 23.

INTERNATIONAL SEARCH REPORT

International Application No.

PCT/GB 97/01232

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61M5/24 A61M5/32

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)
IPC 6 A61M

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

Electronic data base consulted during the international search (name of data base and, where practical, 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.
Y	US 5 320 606 A (JORE) 14 June 1994 see the whole document	1,13,14
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Y	EP 0 581 523 A (INJECT DEVELOPMENT LIMITED) 2 February 1994 see page 3, line 54 - line 56 see figures see page 4, line 42 - line 51	1,13,14
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☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search

3 September 1997

Date of mailing of the international search report

12. 09. 97

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Internat. Application No

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