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ABSTRACT

An IV catheter apparatus including: a catheter hub having a catheter tube extending distally thereof; a needle hub having a needle with a shaft and a tip extending distally of the needle hub and extending through the catheter hub and the catheter tube with the needle tip extending beyond the catheter tube, the needle having an irregularly configured portion on the needle shaft slightly proximal of the needle tip; a needle guard disposed within the catheter hub and having a ready position in which the needle guard is positioned proximally of the needle tip and a protective position in which the needle guard blocks the needle tip, the needle guard having two resiliently movable arms which are urged apart in the ready position; and a detent disposed within the catheter hub for holding the needle guard in the catheter hub in the ready position, wherein the needle guard has a wall proximal and transverse of the arms and through which the needle shaft passes, and means associated with the wall to engage the irregularly configured portion after a portion of the needle shaft which is proximal of the irregularly configured portion is retracted through the wall to draw the needle guard proximally with the needle tip blocked.

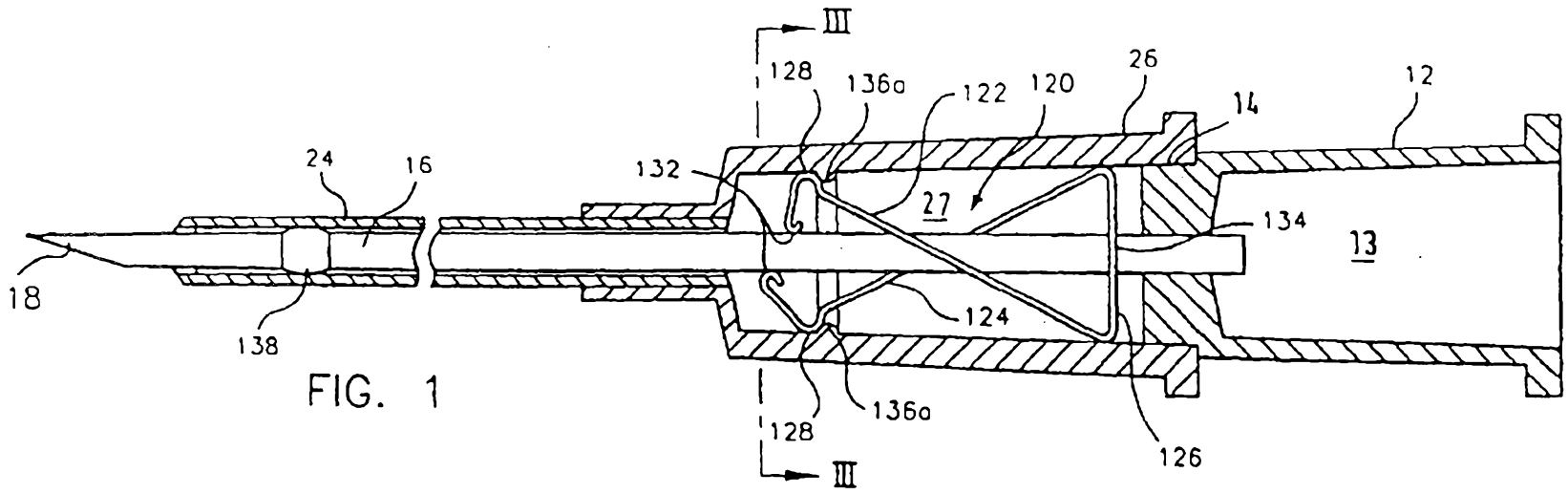
III
128
136a
122
120
26
14
12
24
16
132
27
134
13
18
138
124
128
136a
126
III

FIG. 1

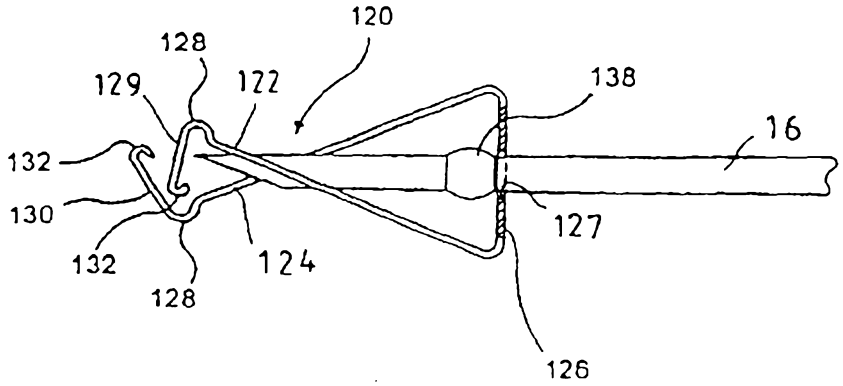
120
128
129
122
138
16
132
130
127
132
124
128
126

FIG. 2

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IV CATHETER

The disclosure of the complete specification of Australian Patent Application No. 2013202166as originally filed is incorporated herein by reference.

The invention relates to a safety needle assembly which can form part of a safety intravenous (IV) catheter device. Safety IV catheter devices comprise a needle protecting means which slides to the needle point as the needle is removed from the catheter and permanently blocks the needle point such that the needle point cannot be inserted into objects or persons.

A safety intravenous catheter device is disclosed in International application WO 99/08 742 by the present applicant. Said catheter device comprises a tubular catheter having a catheter hub at the proximal end, a hollow needle adapted to be inserted into the catheter and provided with a needle hub at the proximal end, and a needle protecting means. The needle protecting means is located in a hollow space of the catheter hub, the hollow space being closed by the needle hub, wherein the needle passes through the needle protecting means and the needle protecting means comprises a spring portion made of steel through which the needle is adapted to slide. The needle protecting means comprises an engagement element which, when the needle is retracted relatively to the catheter, engages with an irregularly configured portion of the needle in order to remove the needle protecting means from the proximal end of the catheter hub. The needle protecting means comprises a bent sheet-metal portion made from spring steel which presses against the wall of the hollow space of the catheter hub, the sheet-metal portion thus being supported. Said support is no longer given when the needle protecting means is moved over the needle point when the needle is retracted, the needle protecting means thus being protected. Then the needle protecting means, together with the needle, can be removed from the hollow space of the catheter hub. In the case of the known catheter device the projection, with which the needle protecting means lockingly engages, is configured as a

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retaining protrusion molded to the inner wall of the catheter hub, or a retaining groove.

A catheter device of this type protecting means poses the problem that the needle protecting means must be fastened in the catheter hub, with a bend or an elbow of the needle protecting means having to be moved over the projection on the inner side of the catheter hub, such that a reliable support of the needle protecting means in the hollow space of the catheter hub is ensured.

It is an object of the present invention to provide an intravenous catheter device comprising a needle protecting means where fastening of the needle protecting means in the catheter hub is facilitated.

An IV catheter apparatus including: a catheter hub having a catheter tube extending distally thereof; a needle hub having a needle with a shaft and a tip extending distally of the needle hub and extending through the catheter hub and the catheter tube with the needle tip extending beyond the catheter tube, the needle having an irregularly configured portion on the needle shaft slightly proximal of the needle tip; a needle guard disposed within the catheter hub and having a ready position in which the needle guard is positioned proximally of the needle tip and a protective position in which the needle guard blocks the needle tip, the needle guard having two resiliently movable arms which are urged apart in the ready position; and a detent disposed within the catheter hub for holding the needle guard in the catheter hub in the ready position, wherein the needle guard has a wall proximal and transverse of the arms and through which the needle shaft passes, and means associated with the wall to engage the irregularly configured portion after a portion of the needle shaft which is proximal of the irregularly configured portion is retracted through the wall to draw the needle guard proximally with the needle tip blocked.

Hereunder embodiments of the present invention are explained in detail with reference to the drawings in which:

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Fig. 1 shows a longitudinal section across a first embodiment of an intravenous catheter device according to the invention,

Fig. 2 shows the distal end of the needle with the needle protecting means protecting the needle point when the needle has been removed from the catheter,

Fig. 3 shows a section along line III-III of Fig. 1,

Fig. 4 shows a similar representation as Fig. 3 of a second embodiment having an essentially annular projection with a small interruption,

Fig. 5 shows a section across a third embodiment with a bipartite annular projection whose segments are separated from each other by two interruptions,

Fig. 6 shows a schematic side view of the distal area of the needle shown in Fig. 1,

Fig. 7 shows a view of the needle shown in Fig. 6 as seen from the direction indicated by arrow VII,

Fig. 8 shows a perspective representation of a tool for fastening the needle protecting means for one embodiment of the invention,

Fig. 9 shows a schematic cross-section of another embodiment of the invention with the needle protecting means being oriented such that it can be inserted into the hollow space of the catheter hub, and

Fig. 10 shows by way of the same representation as Fig. 9 the condition of the needle protecting means after a rotation by approximately 45° with the needle protecting means gripping behind the segments of the projection and being in engagement with the projection.

The embodiment of the present invention shown in Fig. 1 comprises an elongate hollow tubular catheter 24 concentrically connected at its proximal end (remote from the patient) with the distal end of a catheter hub 26. The catheter hub 26 has

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a tapered cylinder 141 defining a hollow space 27 communicating with the volume of the catheter 24 and being open at the proximal end.

The needle 16 passes through the catheter 24. The needle 16 is an elongate hollow needle made of steel and comprising a needle point 18 at the distal end. At a certain distance from the distal end 18 an irregularly configured portion 138 is provided. In the present embodiment said irregularly configured portion 138 is a flattened or crimped section of the needle which increases the width of the needle in one direction and decreases it in the direction perpendicular thereto. Said irregularly configured portion 138 can alternatively be a local projection.

At the proximal end of the needle 16 a needle hub 12 is attached which has a hollow space 13 communicating with the volume of the needle. The distal step in said needle hub 12 abuts the proximal end of said catheter hub 26. In this position of the needle hub 12 relative to the catheter hub 26 the distal end of the needle 16 and the needle point 18 project from the distal end of the catheter 24.

On the needle point 18 a needle protecting means 120 is provided which is configured generally in the same way as the needle protecting means shown and described in Figs. 10A, 10B and 11 of WO 99/08 742. However, the needle protecting means may also be of different configuration and numerous configurations are suggested by the prior art. In particular the needle protecting means needs not comprise any clamping means for clamping the needle in the locked position.

The needle protecting means 120 which is shown in the ready condition in Fig. 1 and in the protecting condition in Fig. 2 is an integral part made of spring steel. It comprises a rear or proximal wall 126 extending transversely to the needle 16 and containing an opening 139 having a continuous perimeter. Said opening forms the engagement element 127 engaging with the irregularly configured portion 138 of the needle 16. Said opening or engagement element 127 is dimensioned such that it can be freely shifted on the needle 16 but cannot pass the irregularly configured

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portion 138. Consequently, the rear wall is shiftable in the area between the irregularly configured portion 138 and the needle hub 12.

From the ends of the proximal wall 126 of the needle protecting means 120 arms 122 and 124 project distally and cross or intersect each other, with each arm 122,124 being resiliently movable and located on a different side of the needle 16 so as to be urged apart in the ready position. At the end of each arm 122,124 an end wall 129,130 is arranged orthogonally to the arm. At the transition between the arm and the end wall a bend 128 or elbow oriented towards the outside is located. At the free end of the front wall 129 and 130, respectively, a lip 132 bent by more than 90° is provided. The arm 122 is shorter than the other arm 124 such that the front walls 129,130 do not collide with each other in the protected condition of the needle protecting means. The front walls 129 and 130 are wider than the arms 122,124 such that, in said protecting condition, they can cover the needle point 18 and protect it against contact with other parts or bodies.

The needle protecting means 120 is retained in the catheter hub 26. For this purpose a detent in the form of an annular projection 136a extending about the inner wall of the catheter hub 26 is provided. While the lips 132 press against the outer wall of the needle 16 from opposite sides (Fig. 1), the bends 128 grip behind the projection 136a. When the needle 16 is removed from the catheter 24 the needle protecting means 120 is retained in the catheter hub 26 such that the needle 16 slides through the catheter hub. When the needle point passes the lips 132 the arms 122,124 resiliently move into the position shown in Fig. 2 in which the front walls 129,130 cover the needle point. In this condition the engagement element 127 abuts the irregularly configured portion 138 such that the needle protecting means 120 is prevented from sliding beyond the distal end of the needle 16. In the embodiment shown in Fig. 1 the projection 136a is of completely round and continuous configuration. The annular projection 136a retains the needle protecting means 120 in the catheter hub 26 when the needle 16 is removed from the catheter hub 26 until the arms 122,124 of the needle protecting means 120 are no longer supported by the needle 16 and resiliently move towards the inside.

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Here, the projection 136 is integrally molded to the catheter hub 26, e. g. by injection molding.

In the embodiment shown in Fig. 4 the projection 136b oriented towards the inside is of generally C-shaped configuration. Said C-shaped projection 136b can be made from a metal snap ring partially seated in an annular groove on the inside of the catheter hub. In this way it is possible to produce the projection 136b by inserting the snap ring into the catheter hub 26 until it lockingly engages the corresponding groove.

Fig. 5 shows another alternative where the projection 136c is divided into two segments with intermediate interruptions 137. Each segment has a larger circumferential extension than the intermediate interruptions 137. Further, the circumferential extension is considerably larger than the width of the distal front walls 129,130 of the needle protecting means. Preferably, the generally annular projection projecting towards the inside does not have any interruptions 137 whose width is larger than the width of the distal front walls 129 and 130, respectively, of the needle protecting means. The interruptions 137 being dimensioned such that they are smaller than the width of the front walls prevents the needle protecting means 120 from unintentionally passing the interruptions 137 thus sliding out of the catheter hub without covering the needle point. According to the present invention any number of separate segments forming a generally annular projection may be provided as long as the needle protecting means 120 is securely retained in the catheter hub when the needle 16 is removed from the catheter 24.

As shown in Figs. 6 and 7 the irregularly configured portion 138 of the needle 16 is preferably produced by deformation, with two bulges 138a oriented in opposite directions and at right angles thereto two dents 138b also located opposite each other being produced. The bulges 138a have a width W which is small enough to allow the needle 16 to move in the catheter 24 as shown in Fig. 1, but which is too

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large to pass the opening forming the engagement element 127 in the basis wall 126 of the needle protecting means 120.

The catheter device according to Fig. 1 is assembled by pushing the needle protecting means 120 over the point 18 of the needle 16 before the irregularly configured portion 138 is produced on the needle. The needle 16 then passes the engagement element 134 which is an opening in the basis wall 126 of the needle protecting means 120. The distal arms 132 are pressed apart and the needle 16 passes between them. Then the irregularly configured portion 138 is produced on the needle 16 such that the needle protecting means 120 is captured between the irregularly configured portion 138 and the needle hub.

Then the needle 16 and the needle protecting means 120 located thereupon are inserted into the catheter hub 26 such that the acute needle point 18 enters the catheter 24. The needle 16 is inserted into the catheter 24 to such an 5 extent that the bends 128 of the needle protecting means abut the projection 136a.

When the bends 128 abut the annular projection 136a the advance movement of the needle protecting means is stopped. This advance movement may also 10 be stopped earlier since the inner wall of the catheter hub 26 tapers such that the needle protecting means 120 is compressed during its advance movement. If the needle protecting means 120 cannot be advanced, a tool is used for advancing the needle protecting means 120 further into the catheter hub 26 until the bends 128 of the needle protecting means 120 lockingly engage with the projection 136a. For this purpose an adequate force must be exerted by the tool on the needle protecting means 120 such that the bends 128 resiliently move towards each other to move over the projection 136a. Then they move towards the outside again and press against the inner wall of the catheter hub 26. The needle protecting means 120 is now in the ready position as 20 shown in Fig. 1.

The tool for inserting the needle protecting means may have any suitable form. Preferably, the tool shown in Fig. 8 is used which comprises a simple pin 200 having a longitudinal slot 202 extending over the overall length. The tool 200 can

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accommodate the needle 16 in said slot 202 while advancing the needle protecting means 120.

The annular projection 136a retains the needle protecting means 120 when the needle is retracted until the lips 132 of the needle protecting means 120 lockingly engage with the needle point such that the bends 128 work free from the annular projection 136a and the needle protecting means, together with the needle 16, can be removed from the catheter hub 26.

An alternative method of assembling the intravenous catheter comprising a spring clip according to the present invention is realized by employing the embodiment shown in Fig. 4 where the projection 136b is an open snap ring. In this case the open snap ring can be slipped onto the needle protecting means such that it is positioned between the proximal end and the distal end of the needle protecting means. Prior to this the needle protecting means 120 has been slipped onto the needle 16 which is then deformed to produce the irregularly configured portion 138. Thereafter the needle protecting means 120 and the open ring 136b are simultaneously inserted into the catheter hub 26 by means of the same tool.

Said tool preferably comprises two fingers each of which extends along one side of the needle protecting means 120. Using these fingers the open ring 136b is pushed further into the catheter hub than the proximal end of the needle protecting means 120. Thus it is not necessary to push the needle protecting means 120 over the annular projection 136b. On the contrary, the needle protecting means 120 and the annular projection 136b are inserted together. Thus the annular projection 136b is inserted into the catheter hub 26 such that the needle protecting means 120 lockingly engages with said lockingly annular projection 136b and remains in that condition until the needle 16 is retracted.

Figs. 9 and 10 show another embodiment of the device, which allows a different fastening method. Here, the annular projection 136d is configured such that it comprises at least 4 interruptions 137 between the segments, with the corners 250 of the needle protecting means 120a being adapted to be pushed through the

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interruptions 137 at a low force or no force at all. When the needle protecting means 120a has been inserted into the catheter hub 26 until it is positioned behind the projection 136d, the needle protecting means 120a is rotated such that the four corners 250 are positioned behind the segments of the projection 136d as shown in Fig. 10. Thus the needle protecting means 120a is retained in the catheter hub 26 until the needle 16 is retracted.

It may be appropriate to configure the needle protecting means 120 such that it has a generally square profile, as shown in Figs. 9 and 10, but other rectangular or polygonal contours of the needle protecting means 120a are also suitable. It is merely necessary to arrange the interruptions 137 of the projection 136d such that the needle protecting means 120 can be easily pushed through said interruptions 137 and then lockingly engages with the projection 136d when the needle protecting means 120a has been rotated such that the corners 250 abut the segments of the projection 136d.

Throughout this specification and the claims which follow, unless the context requires otherwise, the word "comprise", and variations such as "comprises" and "comprising", will be understood to imply the inclusion of a stated integer or step or group of integers or steps but not the exclusion of any other integer or step or group of integers or steps.

The reference in this specification to any prior publication (or information derived from it), or to any matter which is known, is not, and should not be taken as an acknowledgment or admission or any form of suggestion that that prior publication (or information derived from it) or known matter forms part of the common general knowledge in the field of endeavour to which this specification relates.

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THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. An IV catheter apparatus including:

a catheter hub having a catheter tube extending distally thereof;

a needle hub having a needle with a shaft and a tip extending distally of the needle hub and extending through the catheter hub and the catheter tube with the needle tip extending beyond the catheter tube, the needle also having an irregularly configured portion on the needle shaft slightly proximal of the needle tip;

a needle guard disposed within the catheter hub and having a ready position in which the needle guard is positioned proximally of the needle tip and a protective position in which the needle guard blocks the needle tip, the needle guard having two resiliently movable arms which are urged apart in the ready position; and

a detent disposed within the catheter hub for holding the needle guard in the catheter hub in the ready position,

wherein the needle guard has a wall proximal and transverse of the arms and through which the needle shaft passes, and means associated with the wall to engage the irregularly configured portion after a portion of the needle shaft which is proximal of the irregularly configured portion is retracted through the wall to draw the needle guard proximally with the needle tip blocked.

2. The IV catheter apparatus of claim 1, wherein the arms extend distally of the wall.

3. The IV catheter apparatus of claim 1 or claim 2, wherein the arms further include a radially extending member that moves radially to block the needle tip when in the protective position.

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4. The IV catheter apparatus of claim 3, wherein the radially extending member is a guard wall of at least one arm which terminates in a lip engaging the shaft of the needle in the ready position.

5. The IV catheter apparatus of claim 4, wherein the needle urges the arms apart and against the detent to hold the needle guard in the ready to use position.

6. The IV catheter apparatus according to any one of the preceding claims, wherein the means associated with the rear wall is an opening formed in the rear wall through which the needle passes.

7. The IV catheter apparatus of claim 6, wherein the irregularly configured portion engages the needle guard as the needle is retracted.

8. The IV catheter apparatus according to any one of the preceding claims, wherein the irregularly configured portion is a crimped section of the needle shaft which increases the width of the needle in one direction.

9. The IV catheter apparatus according to claim 4, wherein the distal ends of the arms each include a curved protrusion extending to the guard wall.

10. The IV catheter apparatus of claim 9, wherein the curved protrusions are received against the detent.

11. The IV catheter apparatus of claim 10, wherein the detent is an annular groove or ring formed in an inner wall of the catheter hub.

12. The IV catheter apparatus according to any one of the preceding claims, wherein the needle guard is made from a metallic material.

13. The IV catheter apparatus according to any one of the preceding claims, wherein the two arms have dissimilar lengths.

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14. The IV catheter apparatus according to any one of the preceding claims, wherein the two arms intersect the needle axis in the ready to use position.

15. The IV catheter apparatus of according to claim 12, wherein the needle guard is made entirely of metal.

16. The IV catheter apparatus according to any one of the preceding claims, wherein the needle is attached to the needle hub.

17. The IV catheter assembly according to any one of the preceding claims, wherein the catheter hub includes a tapered cylinder having an open end.

18. The IV catheter assembly according to any one of the preceding claims, wherein the needle guard separates from the catheter hub as the arms spring to the protective position.

19. The IV catheter assembly according to any one of the preceding claims, wherein the needle guard is an integrally formed unit.

20. The IV catheter assembly according to any one of the preceding claims, wherein there is a hinged arrangement between the arms and the proximal wall.

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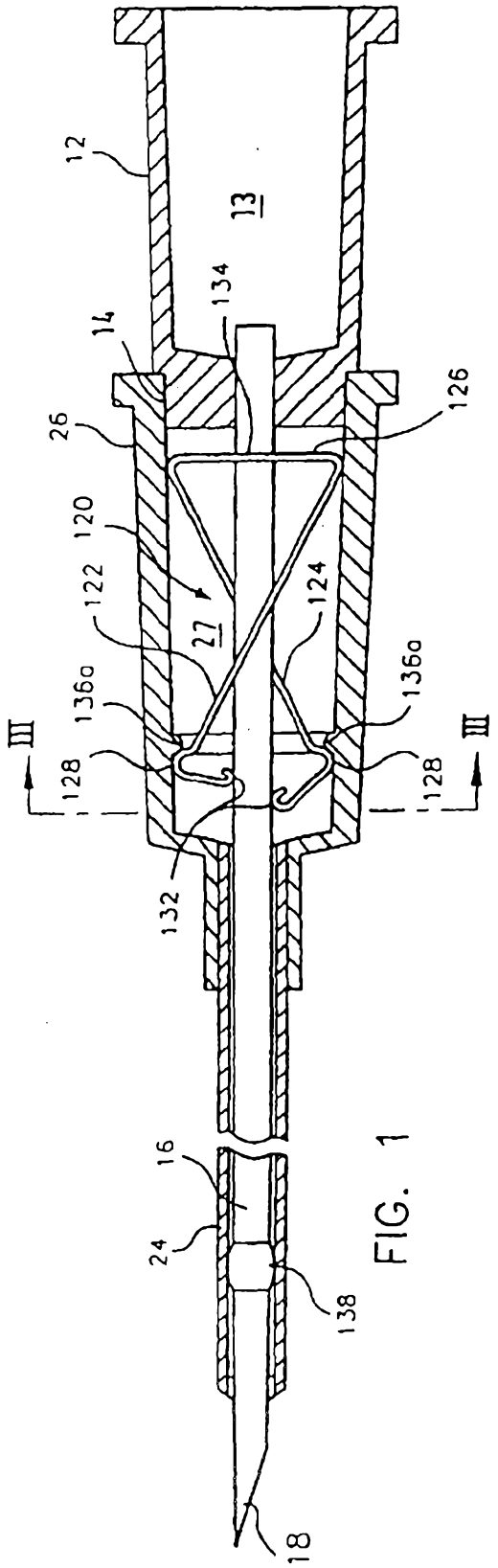

FIG. 1

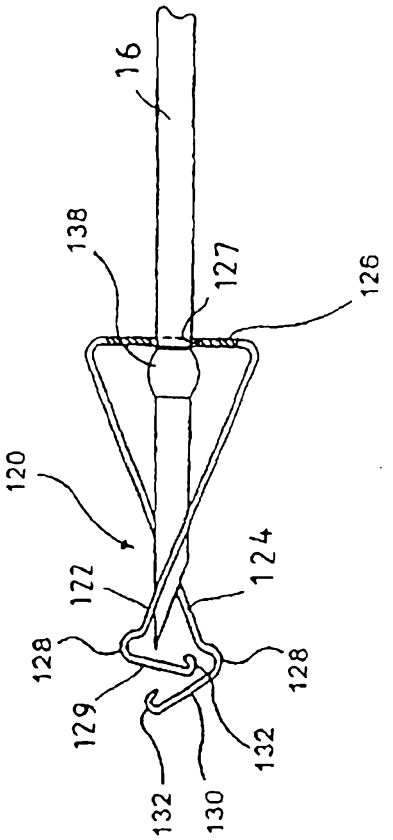

FIG. 2

FIG.3

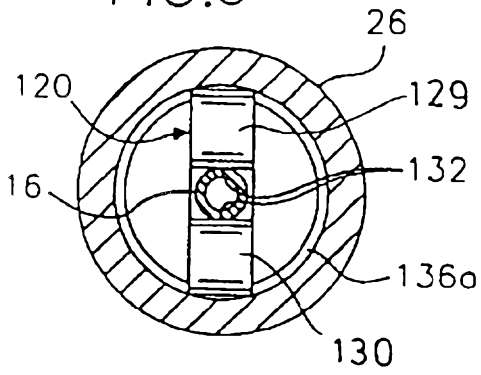

FIG.4

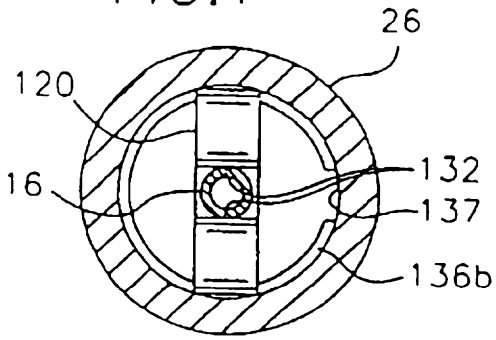

FIG.5

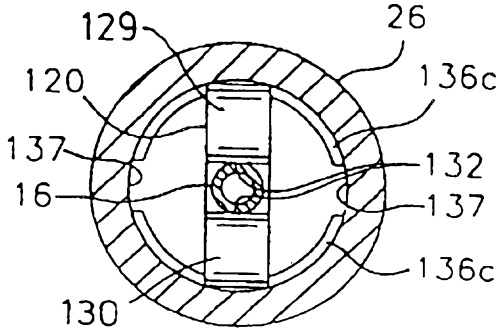

FIG.6

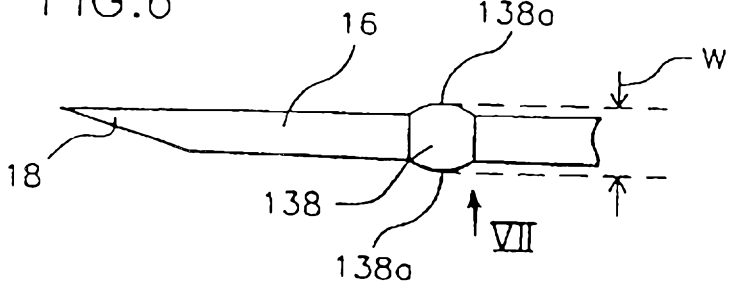

FIG.7

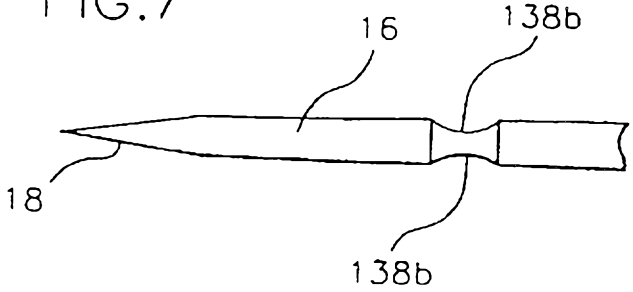

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FIG.8

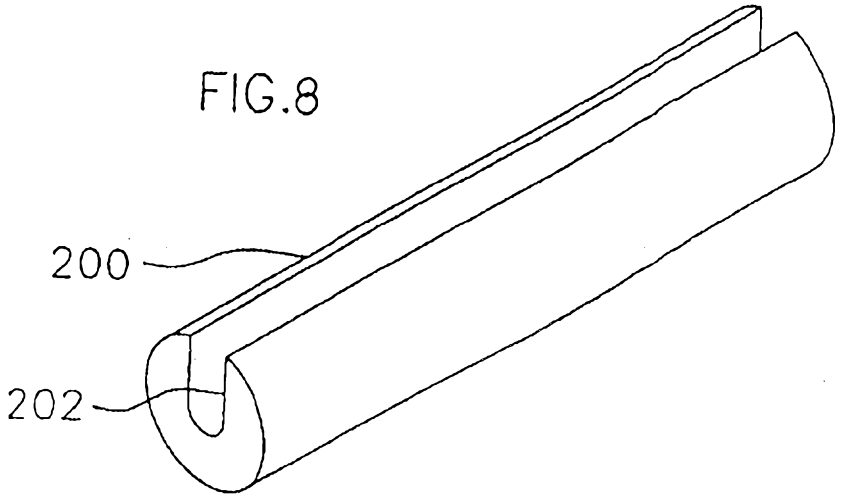

FIG.9

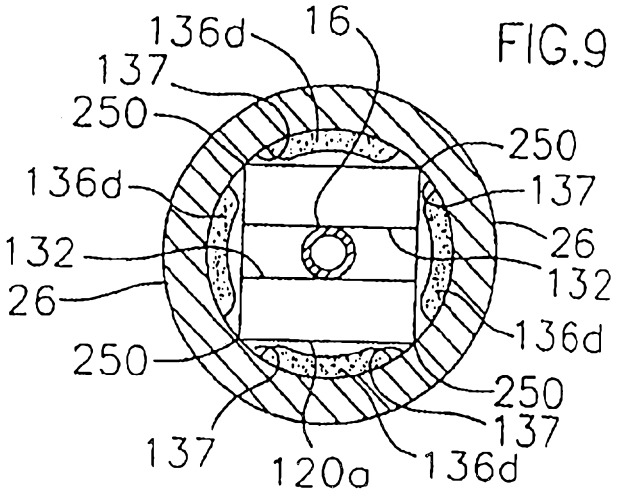

FIG.10