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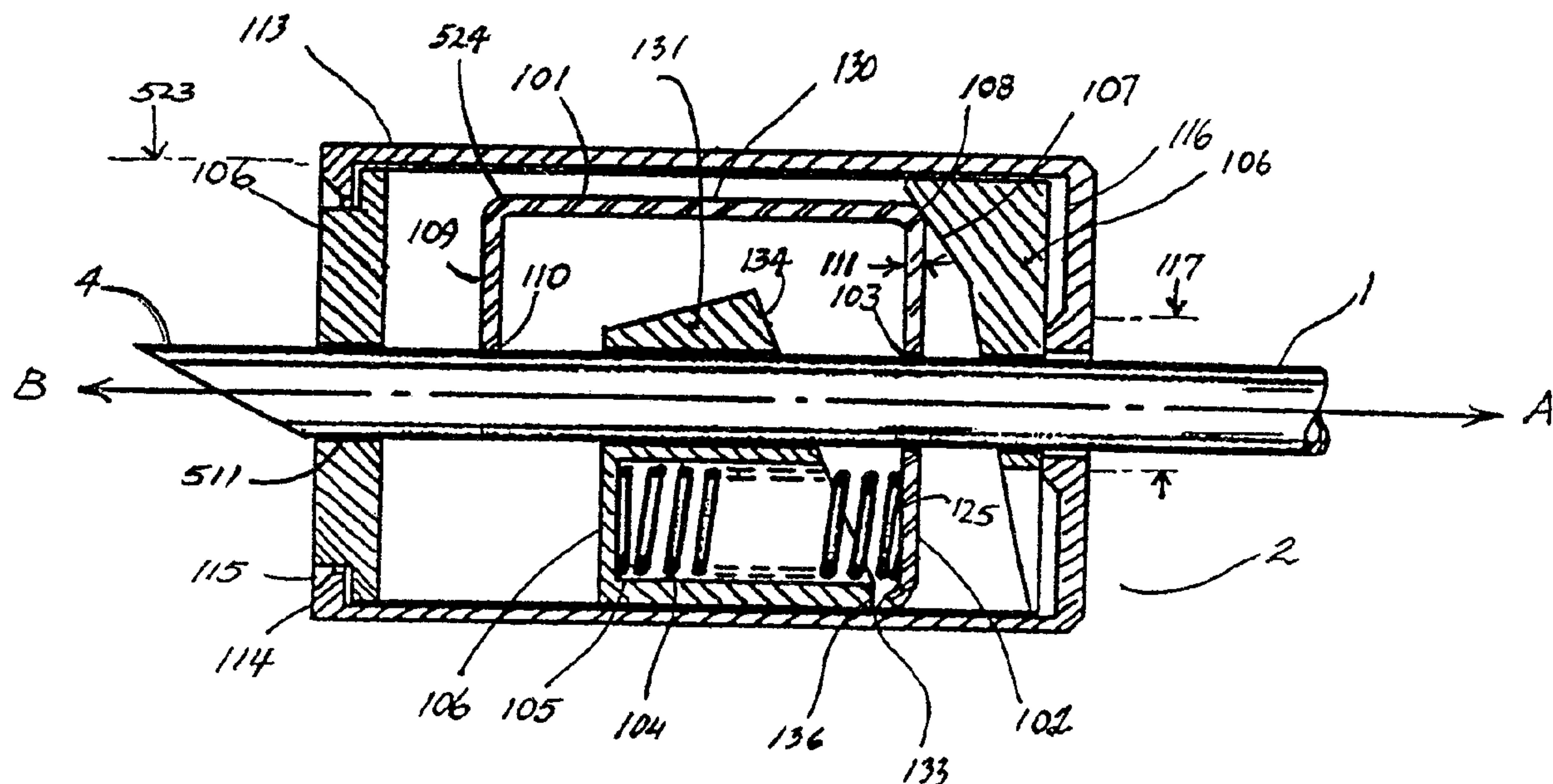
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(54) Titre : GAINÉ D'UNE AIGUILLE HYPODERMIQUE MONTEE SUR AIGUILLE

(54) Title: NEEDLE-MOUNTED HYPODERMIC NEEDLE GUARD



(57) Abrégé/Abstract:

A needle-mounted needle guard that automatically engages with the needle when slid to a tip-covering position may be laterally installed on a needle. Such a device may also be used in a catheter wherein the guard is automatically deposited at the needle tip.

Abstract

A needle-mounted needle guard that automatically engages with the needle when slid to a tip-covering position may be laterally installed on a needle. Such a device may also be used in a catheter wherein the guard is automatically deposited at the needle tip.

Title: Needle-Mounted Hypodermic Needle Guard

Field of the Invention

This invention relates to the safe disposal of hypodermic needles by a guard device which protects the needle tip from exposure after use. More particularly, it relates to a mechanism for a tip protector which is storable on the needle and which automatically locks over the end of the needle when slid into position at the needle tip by the user. Further, this invention concerns an improved needle guard structure and assembly procedure by which the principal components of a needle guard device may be mounted on a needle laterally, from the side, rather than axially from the tip or base end. The invention may also be adapted for use on a catheter.

Background to the Invention

The type of needle guard to which this invention relates has been described in Patent Cooperation Treaty application No. PCT/CA90/00031 published on August 9, 1990 under international publication number WO 90/08564. This prior PCT application describes a range of configurations for needle guard devices which are stored at the base of a needle and which automatically engage with and cover the tip of a needle when moved to the tip.

All of the embodiments in the prior PCT application contemplate installation of the needle guard device on the needle through centrally located and axially aligned holes or passages formed in the device. Such a configuration requires that the devices be installed on the needle by passing the needle centrally through the needle guard devices.

Where metal components are contained within the needle guard device it is preferable to install the device on a sharpened needle from the base end. This is because the sharpened tip of a hypodermic needle must be maintained in a pristine state, and no risk of blunting even a portion of the tip should be allowed as part of the manufacturing process.

The assembly method of installing a needle guard device on a needle from the base end requires that the needle guard be introduced into the hypodermic needle assembly process before assembly is complete. Following the installation of the needle guard on the needle, the manufacturing process customarily requires that the needle be mounted, typically by epoxy glue or thermosetting plastic, in the base.

The necessity for mounting a needle guard device from the base end of a needle would be less pressing if the needle guard components exposed to the needle tip were of softer non-metallic material, such as polymeric plastics. But even with the exposure of the needle tip to only plastic materials, the alignment of a complicated mechanism having small axial passages with a needle is complex and creates difficulties in the assembly process.

10 In the PCT application described above, one of the embodiments of the general invention disclosed therein, the sixth embodiment, is of a configuration that, with modification, may serve as a demonstration of a needle guard that may be installed on a needle laterally, from the side. Such a method of installation decreases significantly the inconveniences described above.

20 In the prior art, U.S. patent No. 4,755,170 to Golden shows a side-mounting cover for a needle tip. That cover comprises a split-cork like device that includes no provision for locking the cover in place when it is positioned over the needle tip. No provision is made to prevent re-emergence of the needle tip. And no provision is made to secure the cover from removal, off the tip-end of a standard needle of constant circumferential diameter.

30 The subject sixth embodiment of the prior PCT application is a needle guard device which is capable of automatically engaging with the outer surface of a needle of constant circumferential diameter and thereby prevent removal of the device from the needle, once it is positioned over the tip. It is also provided with means to prevent re-emergence of the needle tip once the guard is in position, surrounding the tip. This sixth embodiment relies on a "canted plate" to engage and lock onto the needle when the needle guard is moved to the needle tip. This "canted plate" device incorporates a locking plate with a hole therethrough through which the needle passes. This locking plate is canted to engage the needle by the release of the needle-sensing portion of a lever arm extension that is attached to the locking plate.

40 In the PCT application the expression "lever arm" is used to describe both the lever arm extension and locking plate, collectively, described in the earlier patent application as forming a "U"-shaped element. For purposes of definition hereafter, "lever arm" will be used to refer to the middle portion and shorter leg of the "U" collectively; the middle portion of the "U" will be referred to as a "longitudinal bar"; the shorter leg of the "U" will be referred to as the

"sensing leg" of the lever arm, which leg may also serve as a "blocking plate"; and the needle-contacting end on the blocking plate will be referred to as the "sensing end" of the lever arm.

The invention herein in its general form, will next be summarized, and then its implementation in the form of specific embodiments will be detailed with reference to the drawings following hereafter. These embodiments are intended to demonstrate the principle of the invention, and the manner of its implementation. As such they are merely exemplary.

10 The invention will then be further described, and defined, in its most general and more specific forms by means of the series of claims which conclude this Specification. That invention concerns an automatically locking, needle mounted tip protecting needle guard device that permits such a needle guard to be installed on a needle laterally, from the side, and its adaptation to catheters. It also concerns a new configuration for the lever arm that is of improved design.

Summary of the Invention

20 According to the invention, a needle guard is provided that may be installed on a needle of constant circumferential diameter for storage at the base of the needle and which contains:

- (1) engagement means for automatically engaging the outer surface of the needle against further removal of the needle guard from the needle when the needle guard is moved to a position where it covers the needle tip; and
- (2) means to prevent re-emergence of the needle tip from the needle guard when the needle guard is moved to a position where it covers the needle tip,

30 such needle guard further comprising:

- (3) a body having an inner needle passageway throughout the longitudinal length of such body and dimensioned to permit a needle to be passed axially therethrough; and
- (4) an opening provided along one side of the body, over its entire longitudinal length, to provide a needle access opening in the body which will permit a needle shaft to laterally enter and be placed coaxially within the inner needle passageway of said body.

40 In the specific exemplary embodiment described hereafter, the needle guard comprises:

- (1) a locking plate positioned within said cavity, the locking plate having a needle opening pierced transversely therethrough which is aligned with said passageway so as to permit both to be pierced by a needle when a needle is installed within the needle guard body;

(2) alignment means to maintain the locking plate and transverse needle opening in a sliding alignment with the needle while the needle tip is outside of the needle guard; and

(3) canting means to cant the locking plate and needle opening into locking engagement with the needle when the tip enters within the needle guard;

10 the opening in the locking plate being exposed on one side thereof to provide a locking plate needle access opening which will permit a needle shaft to laterally enter and be placed coaxially within the needle opening.

As an optional feature of the invention the needle access opening in the body may be undercut to a width that will allow the needle to be inserted laterally under pressure, but will retain the needle within the inner needle passageway thereafter.

20 As a further optional feature of the invention the locking plate needle access opening may be narrowed in its width to allow the needle to be inserted in the locking plate needle opening under pressure, but retained therein thereafter.

30 As a further optional feature of the invention, the aforesaid canting means includes a spring installed within a spring cavity within the needle guard body, with a first end of the spring being in contact with the body of the needle guard, and the second end thereof being in contact with the alignment means or locking plate so as to apply a canting force to the locking plate, the spring cavity being outwardly accessible through a spring cavity access opening. The spring may be of a spirally-coiled compression type which applies its canting force to the locking plate. Or the spring may be of a torsional type that applies the canting force to the lever arm. Optionally, the spring cavity access opening may open on the same side of said body as the needle-access opening in the body.

By a further optional feature of the invention, the spring cavity access opening is undercut to a width that will allow the spring to be inserted therein under pressure, but will retain the spring within the spring cavity thereafter.

40 As a further optional feature of the invention, the alignment means comprises a rotatable lever arm attached to the locking plate, such lever arm having first and second ends, the first end thereof being attached to the locking plate and the second or needle-sensing end thereof being in contact with and restrained by the shaft of a needle when a needle is installed within the needle guard, the needle-

sensing end of said lever arm comprising a recess which partially embraces the surface of the needle against which it rests.

10 As a further optional feature of the invention, the lever arm comprises a laterally displaced longitudinal bar which extends between its needle-sensing end which rests against the needle and the locking plate, such longitudinal bar being free to rotate with the locking plate in a plane and being located in a position whereby the plane within which the longitudinal bar rotates is laterally displaced from the inner needle passageway within the body of the needle guard.

As a further optional feature of the invention, the lever arm terminates at its second end with a blocking plate portion which is biased by a spring to pass into the axial path of the needle when the needle is drawn past the needle sensing end of the lever arm, blocking re-emergence of the needle. Additionally the blocking plate portion of the lever arm may extend at one of its ends to the upper limit of the needle guard body.

20 As a further feature of the invention a catheter assembly comprising a catheter with a base and an insertion needle passing therethrough is provided wherein the needle guard is:

- (1) frictionally coupled to and retained in association with the base of the catheter, both during storage and deployment of the needle guard, until the needle guard is deployed to a tip-covering position whereupon the needle guard engages with the needle;
- (2) detachable from the base of the catheter upon further removal of the catheter from the insertion needle; and
- 30 (3) mountable on the insertion needle from a lateral position.

The foregoing summarizes the principal features of the invention and its optional aspects. The invention may be further understood by the description of the preferred embodiments, in conjunction with the drawings, which now follow.

Summary of the Figures

40 Figure 1 is a longitudinal cross-sectional view of a canted plate locking device as depicted in the prior PCT application showing the relationship of the parts in the unlocked state.

Figure 1A shows an alternate form of lever arm to that of Figure 1, also previously described in the PCT application.

Figure 2 is a longitudinal cross-sectional view of a

canted plate locking device as depicted in the prior PCT application showing the relationship of the parts in the locked state.

Figure 3 is a partially disassembled top view of the needle guard body, in this improved exemplary embodiment, with components therein, mounted on a needle, and with the outer sleeve coaxially displaced along said needle, prior to final assembly;

10 Figure 4 is a side view of the improved needle guard with a series of three sectional end views taken along the side view;

Figure 5 is a top view of a needle guard in which the longitudinal portion of the lever arm is a lateral bar which is oriented in a plane that is parallel to its plane of rotation; and

Figure 6 is a side view of the needle guard of Figure 5, with two cross-sectional views taken from therein.

Figure 7 is a top view of a needle guard with a different spring configuration.

20 Figure 8 is a front view, with cross-section, of the embodiment of Figure 7.

Figure 9 is a depiction of the catheter assembly with a side-mounting needle guard mounted thereon.

Description of the Preferred Embodiments

30 In Figure 1, the structure of one version of the canted plate version of the needle guard 2 of the prior PCT application is shown. In this Figure the general locking means comprises a pivoting lever arm 101 of stiff material attached to a locking plate 102 to form the general shape of a broad "U" of unequal proportions. The longer portion of the "U" is formed by the locking plate 102 which is provided with a hole 103 of slightly larger diameter than that of the needle shaft 1 sufficient to allow the locking plate 102 to "cant" on the needle 1 as shown in Figure 2. This shorter leg 109 of the lever arm 101 is bent downwardly towards the needle 1. As long as the leg 109 contacts the needle 1, it causes the lever arm 101, of which it is a part, to serve as an "alignment means" for aligning the locking plate 102 in sliding alignment with the needle shaft 1.

40 A helical compression spring 104, also shown in simplified cross-sectional view Figure 1, is contained in a largely compressed state in longitudinal cavity 105 within the guard body 106, with its free end 125 pressing against the locking plate 102, and urging the lever arm 101 axially against the sloping internal face 107 of body 106, making contact at

pivot point 108. The turning moment of the spring force tends to rotate lever arm 101 in a counter-clockwise direction about pivot point 108, but the shorter vertical leg 109 of lever arm 101, referred to as the sensing leg 109, prevents rotation by making contact with the needle shaft 1 at point 110.

Optionally the lever arm 101 may terminate directly in contact with the needle 1 as a modified form of lever arm 101B, as shown in Figure 1A.

10 By appropriate choice of the slope of face 107 in relation to the geometry of lever 101 and locking plate 102, a component of reaction force will be developed to act at pivot point 108 in a downward direction against locking plate 102, equal and opposite to the upward reaction force against the lever arm 101 at point 110. This balancing of vertical forces against locking plate 102 substantially removes any radial force between needle shaft 1 and the walls of hole 103 in locking plate 102, thereby reducing axial frictional drag between the needle and lever when moving the guard device axially along the needle shaft. Alternately, the geometry may
20 be modified to create a degree of frictional resistance, if this is desired.

In Figure 2 the needle shaft 1 is shown withdrawn into the needle guard 2 and past the point of contact with the needle-contacting or sensing end 110 of sensing leg 109 of lever arm 101 and with the needle tip 4 within the needle guard 2. This allows the lever arm 101 to rotate in a counter-clockwise direction, as seen in Figure 2, about pivot point 108 under the urging of spring 104, which rotates the locking plate 102 until further rotation is prevented by the
30 axial misalignment of hole 103 and needle shaft 1. Thus the spring 104, in conjunction with the body 106, serve as a "canting means" to cant the locking plate 102.

By utilizing well-known relationships between the thickness of the locking plate 102, the distance between the pivot point 108 and the centre of the needle shaft 1, the diameter of hole 103, the diameter of needle shaft 1, and the coefficient of friction between locking plate 102 and needle shaft 1, a critical geometry is established, whereby the axial frictional grip between locking plate 102 and needle shaft 1
40 is always greater than an externally-applied axial force on the needle directed to further remove the needle from the guard, shown as direction "A" in Figure 2. Thus further motion of the needle shaft 1 in this direction is prevented by the locking of plate 102 on needle shaft 1, axial motion of the locking plate 102 with respect to the guard body 106 being

blocked by sloping face 107. With increasing applied axial force in direction "A", this locking action will persist until material deformation occurs, distorting the geometry beyond the critical configuration.

10 This self-locking action is normally released if the relative needle motion is reversed to direction "B", by attempting to slide the guard device back onto the needle. However, such motion is blocked by the presence of the sensing leg 109 which serves as a blocking plate in the return path of the needle, preventing re-exposure of the needle point by a substantial obstruction of hardened material. Between these two positions, the spring 104 will continue to maintain the locking plate 102 at a canted angle.

20 Alternately or concurrently, a complementary pivot point 136 may be provided on the guard body 106 adjacent to and on the outward side of the spring 104 as shown in Figure 2. This pressure point 136 is located so as to apply a canting force to a modified locking plate 132 through a contacting flange 133 at the end of the locking plate 102 when the needle is moved in the direction for re-emergence of the tip, i.e., direction "B", thus providing a supplementary locking of the guard body 106 against removal in this direction as well.

30 On initial displacement towards re-emergence, the needle will carry the lever arm 101 forward to the position 101A whereat the contacting flange 133 rests against the complementary pivot point 136, identified in this position as 133A. Any further attempt at displacement will apply the same canting force to the modified locking plate 132. The guard body 131 of Figure 1 is of a length sufficient to provide clearance space for the additional displacement of lever arm 101. Additionally, the surface 134 on the interior body portion 131 is inclined to provide freedom for the modified locking plate 132 to remain canted.

40 To prevent the guard device from being removed forcibly from the needle by its repeated rotation about the needle shaft, the body 106 as shown in Figure 1 is preferably surrounded by loosely-fitting sleeve 113, which provides rotational isolation of the body 106 from the external operating means. Sleeve 113 is retained axially on body 106 by snap lips 114, fitting into a circular rabbet 115 in one end of the body.

Referring to Figure 1, the inner face 116 of sleeve 113 is optionally relieved over most of its surface to make axial contact with body 106 only over a small diameter 117. This reduces the frictional torque transmitted between sleeve

113 and body 106 by combined axial and rotational force applied to the guard device by the external operating means, thus enhancing its rotational isolation.

The foregoing has constituted a description of the prior PCT device which has been adapted by the invention herein for lateral installation on a needle.

In Figure 3, a modified needle guard 3 incorporating features of the invention is shown in top view. The background version of the needle guard used hereafter to explain the invention relies on the canting plate to lock in one direction only, but the double-locking version may be utilized equally. Further, the embodiment being described is intended to be merely exemplary of a side mounting needle guard which automatically locks onto a needle when moved to the tip.

In this new embodiment, a portion of the guard body 106 is absent on one side, forming an outer cavity 500, as shown in Figure 3. This intersects with and forms part of a radially-disposed slot 501, shown in the three cross-sections of Figure 4 and forming an outer needle access passage 501 in the guard body 106. Slot 501 extends axially the full longitudinal length of the guard body 106, cutting through the two end portions 106A and central portion 106B of the body. As best seen in cross-section C-C, the cylindrical inner needle passageway 511 carries the needle, with a close, sliding fit. The slot 501 penetrates to the inner needle passageway 511 and the width of the intersection 512 which forms the entrance to the needle passageway 511 is somewhat less than the diameter of needle 1, so that the resulting undercut allows a press-fit installation, but retains the needle radially within its passageway 511.

Slot 501 extends radially beyond the needle cavity 511 to form a further penetration 522 into the guard body 106. By thus reducing the remaining cross-section of the body 106, slot extension 522 imparts additional compliance to the body 106, allowing the needle 1 to be inserted laterally from the side by springing open slot 501 sufficiently to allow the needle 1 to pass the constriction at the undercut 512. As shown in cross-section A-A of Figure 4, the needle 1 is positioned in slot 501 during assembly, and then pressed laterally into its central position by an insertion bar 507, which extends the full axial length of the body 106. The necessary springing-open of slot 501 may be aided by widened flanks 513 on insertion bar 507.

A spring access passage 502 is also provided. This is best seen in cross-section C-C of Figure 4. This entrance to

the spring cavity 105 may also be slightly under-cut at 503, sufficiently wide to allow the spring 104 to be pressure-fitted into the cavity 105, and narrowed enough to retain the spring 104 within the cavity 105, once installed.

The spring cavity 105 is shown as having a spring access passage 502 on the same side of the guard body 106 as the needle access passage 501. However, these access passages 501, 502 need not necessarily be on the same side. The spring cavity 105 may optionally be accessed from the reverse side or even from the bottom.

The locking plate 102, attached to the lever arm 101, is also provided with a needle access passage 504, shown in cross-section A-A of Figure 4, that permits a needle 1 to be inserted laterally into the locking plate needle opening 103 which forms a needle passageway through the locking plate 102. The needle access passage 504 in locking plate 102 is preferably located on the side of the lever arm 101 shown in cross-section A-A of Figure 4, so that the needle 1 retains the lever arm 101 laterally in its cavity in body 106.

Alternatively, the needle access passage 504 may be undercut slightly, to provide retention of the lever arm 101 on the needle 1, in the same manner as the entrance 512 to needle passageway 511 in body 106. By twisting the access passage 504 slightly during fabrication, and by correspondingly twisting the needle 1 and lever arm 101 relative to one another during assembly, the needle 1 would be allowed to pass this undercut, for installation in the locking plate needle opening 103. This would allow needle access passage 504 to be located on the opposite side of locking plate 102, thus permitting the lever arm 101 and locking plate 102 to be installed in guard 106 after installation of the needle 1 in same.

The presence of the needle access passage 504 that intersects the locking plate needle opening 103 must not weaken the locking plate's ability to grasp and lock onto the needle 1 when the locking plate 102 is canted. Using mild carbon steel, it has been found that a locking plate of 0.50 mm thickness and 2.5 mm width is reasonably reliably capable of maintaining structural integrity when pierced by a locking hole of 0.9 mm diameter.

As a further optional feature, the sensing end 505 of the shorter, sensing leg 109 of the lever arm 101 may be indented as shown in cross-section B-B of Figure 4, to form a slight notch or recess 506, which may be rounded so as to partially embrace the needle 1. This recess 506 serves to contribute to stability in locating the sensing end 505 on the

- 11 -

needle 1. Such a recess 506 may also be formed in the needle-contacting end of the configuration of needle arm 101A shown in Figure 1A.

The locking plate end 509 of the locking plate 102 may also optionally be provided with a small spur 510, as shown in cross-section A-A of Figure 4, which interfits with the end of the helical spring 104. This spur 510 further helps to locate and stabilize the engagement of the spring 104 and the lever arm 101.

The assembly procedure for this lateral or side-mounting version of the needle guard may then be as follows:

1. The spring 104 is inserted laterally into its cavity 105, by snapping it into place past its undercut 503 from the side, as shown in cross-section C-C of Figure 4.
2. The spring 104 is then compressed by a thin depressor finger (not shown) so that its right end is flush with the open end of its cavity 105.
3. The lever 101 is inserted from the side, oriented in approximately its locked position to clear the depressor finger.
4. The depressor finger is removed, allowing the spring to engage the spur 510 on the locking plate end 509 of the lever arm 101.
5. A lever depressor (not shown) approaches from the right to engage the locking plate 509 end of the lever 101 and rotate it into its unlocked position as shown in Figure 4.
6. The outer sleeve 113 is placed over the needle 1 and positioned towards the needle base, and the two are positioned so that the needle is along-side and parallel to the axis of the body 106, ready to enter the access slot 501, as shown in cross-section A-A of Figure 4.
7. The needle 1 is moved into position from the side, accompanied by sleeve 113, and is pressed into the central needle passageway 511, by a suitable insertion bar 507 extending the length of the needle guard body 106. This is shown in cross-section A-A of Figure 4. The bar 507 may have widened flanks 513 to engage the tapered sides 514 of the access passage 501 and expand it sufficiently to allow easy needle entry.
8. The lever depressor is removed, and the entire inner assembly may then be pressed into place within the outer shell or sleeve 113.

As indicated by step six above, before assembly of the guard body 106 onto the needle 101, the outer sleeve 113 may be installed by sliding it axially over the needle 1. Because this part may be made of plastic and may have enlarged holes

on its ends, this component may be more easily passed axially over the needle 1 from either of its two ends. If passed over the sharpened tip end, the enlarged holes will allow for less critical mechanical assembly. As well, being made of plastic, the sleeve 113 will not damage the sharpness of the tip of the needle 1.

10 As an alternate procedure the sleeve 113 may be formed with a separation line that permits it to be elastically expanded and to pass around the needle from a lateral position. As a further alternate procedure the sleeve 113 may be made of two parts that are fastened together after being placed around the guard body.

The assembly procedure described was premised on a version wherein the outer access passage 500, lever arm access passage 504 and spring access passage 502 are all on the same side. A correspondingly adjusted assembly procedure would be followed where the location of any of these access passages is reversed.

20 A principal advantage of the foregoing procedure, and of the invention, is that it may be applied to needles for hypodermic syringes or catheters, or needles and syringes, after these components have been fully manufactured. Thus, there need be no intervention in the already-existing production process.

Referring now to Figure 1, for secure operation the sensing leg 109, formed at the end of the lever arm 101, must be large enough vertically to ensure that:

- 30 (1) in swinging into the path of the needle 1 to assume its locked position, the sensing leg 109 will fully block the needle path; and
- (2) the further swinging of the lever arm 101 for a significant distance beyond its locked position is not obstructed by the lever arm coming into contact with the needle 1 or the body 106.

This latter provision is necessary to accommodate variations in the locked position of the lever arm, caused by manufacturing tolerances and by deformations of the various components of the needle guard.

40 In the prior art of Figure 1, the longitudinal bar 130 portion of the lever arm 101 is shown in a position wherein its principal, centrally located plane of rotation passes through the needle 1, and the needle passageway 511. As shown in Figure 3 this longitudinal bar 130 is joined integrally at a bend 524 to the sensing leg 109, which also serves as a needle-blocking plate 109. In this configuration, the sensing leg 109 does not occupy the full vertical space of the interior cavity

in the body 106, up to its outer cylindrical boundary 523.

In Figure 4, cross-section B-B, the greater the width of the blocking plate 521 portion of the lever arm 101 is (to provide security in blocking the needle 1), the more waste space 526 occurs in the circular segment formed between the upper surface 525 of the lever arm 101 and the outer cylindrical boundary 523 of the body 106. Further waste space is formed by the thickness 528 of the lever arm 101, as shown in cross-section A-A of Figure 4.

10 To better utilize the interior space, and thus increase the available lever arm swing for a given size of needle guard body, it is advantageous to lengthen the blocking plate 521, so that it extends to its full vertical limit, up to the outer cylindrical boundary 523 of the guard body 106.

One means that might be considered for doing this would be to add an extension flange that extends into the waste space 526. However, this provides no advantage, as lever arm 101 cannot swing far enough to utilize this additional blocking plate area, because longitudinal bar 130 prevents the necessary additional rotation by striking the
20 needle 1 or central portion 106B of body 106.

An alternative embodiment is shown in Figures 5 and 6. In this arrangement, the longitudinal bar 130 of the prior art arrangement has been relocated by rotating it 90 degrees into an orientation 130A. In this location the principal plane of rotation of this relocated longitudinal bar 130A is laterally displaced from the central needle passageway 511 formed in the guard body 106. This is conveniently accomplished by
30 attaching the longitudinal bar (referred to sometimes hereafter in such configuration as a "lateral bar" 130A) to the edges of the locking plate 102A and blocking plate 521A. These connections are preferably effected at positions that are inward from the ends of such latter components. Conveniently these connections may also be made at the ends of the longitudinal bar 130A, but may also be attached inwardly from such ends. By making the connections at the outermost ends of the longitudinal bar 130A the locking plate 102A, lateral bar 130A and blocking plate 521A may then be bent from
40 a single stamped sheet, and the blocking plate 521A may extend fully to the limit of the cylindrical boundary 523 of the guard body 106.

The lever arm 101A of this configuration may thus be described as having two components:

- (1) a longitudinal bar 130A attached at one end to the locking plate 102A; and

- (2) a needle-sensing leg 109 which serves as a blocking plate 521A, joined to the other end of the longitudinal bar 130A.

Alternately, the needle-sensing leg 109 and blocking plate 521A may be separate elements, for instance, where the needle-sensing leg 109 is formed inwardly of the blocking plate 521A.

10 The lateral bar configuration for the lever arm 101A can serve equally in a needle guard which is not characterized by an inner needle passageway 511 which is open on one side of the needle guard body 106. Thus, this lateral bar configuration may be applied directly to the design of the sixth embodiment described in PCT Application CA 90/00031. The advantage of use of a lateral bar 130A in the earlier design is the increased flexibility provided for choosing the dimensions of the needle guard.

In Figures 6 and 7 an alternate configuration for the spring is depicted.

20 Instead of a compressional spring 104, Figures 6 and 7 depict use of a torsional spring 104A. The torsional spring 104A is mounted in a circular recess 540 within the body 106 of the needle guard. The helical axis of the torsional spring 104A is oriented in a direction which is parallel to the direction of the plane of rotation of the laterally mounted longitudinal bar 130A (in the sense that the direction of a plane is defined by the direction of a perpendicular thereto).

30 One end 542 of the torsional spring 104A is anchored in a slot 543 within the needle guard body 106. The other end 544 is extended to provide a grasping arm 545 that is engaged with the longitudinal bar 130A by means of a hooked-end 546 formed at its free end. This hooked end 546, together with a suitable spring geometry, enables the grasping arm 545 to bias the longitudinal bar 104A to rotate in the manner described previously.

A further alternate spring arrangement could employ a leaf or bowed spring, set into a cavity in the body 106 above the lever arm 101 from whence it may press downwards on to the longitudinal bar 130. Where a lateral bar 130A is employed, an extension from this linear spring would engage the bar 130A.

40 These configurations have the disadvantage of applying an off-centered, twisting force to the lever arm 101. The lever arm 101 may be stabilized by setting the pivot point 108 of the locking plate 102 into a slight recess 547 formed in the face 107 of the body 106 against which the locking plate 102 rotates. Alternately or concurrently, the

grasping arm 545 of the torsional spring 104A may overlies the longitudinal bar 130A or the hooked end 546 may be provided with an extension 548 that overlies the longitudinal bar 130A.

10 In Figure 9 a catheter assembly of the intravenous type is shown carrying a side-mounting needle guard 2 of the type described herein as being exemplary of the principle of the invention. The outer shell 113 of the guard 2 extends over and is frictionally retained on the base portion 119 of the catheter 118 of the catheter assembly. The insertion
needle 1 extends through the guard 1 and catheter 118 to emerge slightly beyond the distal end 120 of the catheter 118.

The inner diameter 121 of the extended portion of the shell 113 is such as to provide a frictional coupling with the guard 1 that will carry the guard 2 with the catheter 118 as the insertion needle 1 is withdrawn from the catheter 118. Upon reaching the point where the guard 2 encloses the tip 4, the guard will engage automatically with the needle. Thereafter further separation of the needle 1 and catheter 118 will cause the guard 2 to detach from the base portion 119 of
20 the catheter 118, leaving the guard 2 on the needle 1 in its tip-protecting position.

Conclusion

The foregoing has constituted a description of specific embodiments showing how the invention may be applied and put into use. These embodiments are only exemplary. Persons skilled in the art will be capable of adopting modifications to the embodiments described which will serve as equivalents, but still utilize the invention as set forth herein. The invention in its broadest, and more specific
30 aspects, is further described and defined in the claims which now follow.

THE EMBODIMENTS OF THE INVENTION IN WHICH AN EXCLUSIVE
PROPERTY OR PRIVILEGE IS CLAIMED ARE DEFINED AS FOLLOWS:

1. A needle guard (2) for installation on a needle (1)
having a base and a tip (4) for initial storage at the base of
5 the needle and subsequent advancement to cover the needle tip
comprising:
 - (a) a body (106) having a longitudinal length and an
inner needle passageway (511) extending throughout
the longitudinal length of such body (106), said
10 passageway (511) being dimensioned to permit a
needle (1) to be passed axially therethrough;
 - (b) a longitudinal slot (501) provided along one side of
the body (106), to provide a needle access opening
(501) in the body which will permit a needle shaft
15 (1) to laterally enter and be placed coaxially
within said needle passageway (511) of the body
(106);
 - (c) engagement means for automatically engaging the
outer surface of the needle (1) and rendering the
20 needle guard (2) non-removable from the needle (1)
when the needle guard (2) is moved to a position
where it covers the needle tip (4); and
 - (d) means (521, 133A) to prevent re-emergence of the
needle tip (14) from the needle guard (2) when the
25 needle guard (2) is moved to a position where it
covers the needle tip (4).
2. A needle guard (2) as in claim 1 further comprising:

- 5 (a) a locking plate (102) positioned within a cavity (500), in the body (106), such locking plate (102) having a needle opening (103) therethrough, such needle opening (103) being aligned with the inner needle passageway (511) to permit both to be pierced by a needle (1) when the needle (1) is installed within the needle guard (2);
- 10 (b) alignment means (101, 105) to maintain the locking plate (102) and needle opening (103) in a sliding alignment with the needle (1) while the needle tip (4) is outside of the needle guard (2); and
- 15 (c) canting means (104, 106) incorporating a spring (104) to cant the locking plate (102) and needle opening (103) into locking engagement with the needle (1) when the tip (4) enters within the needle guard (2);

the needle opening (103) in the locking plate (102) being exposed on one side of the locking plate (102) to provide a locking plate needle access opening (504) which will permit a
20 needle (1) to laterally enter and be placed coaxially within the needle opening (103).

3. A needle guard (2) as in claim 2 in which the alignment means (101) comprises a rotatable lever arm (101) attached to the locking plate (102), such lever arm (101)
25 having first and second ends, the first end thereof being attached to the locking plate (102) and the second or needle-sensing end (110) thereof being in contact with and

restrained by the shaft of the needle (1) when the needle (1) is installed within the needle guard (2).

4. A needle guard (2) as in claim 3 wherein the needle sensing end (506) of said lever arm (501) is characterized by
5 a recess (506) which partially embraces the surface of the needle (1) against which it rests.

5. A needle guard (2) as in claim 1, 2 or 3 wherein the needle access opening (501) in the body (106) is undercut to a width that will allow the needle (1) to be inserted
10 laterally under pressure, but will retain the needle (1) within the inner needle passageway (511) thereafter.

6. A needle guard (2) as in claim 2, 3 or 4 wherein the canting means (104) comprises a spring (104) having first and second ends installed within a spring cavity (105) within the
15 body (106), the first end of the said spring (104) being in contact with the body (106) of the needle guard (2), and the second end thereof being in contact with either the alignment means (101) or the locking plate (102) so as to bias the alignment means (101) or locking plate (102) to rotate, the
20 spring cavity (105) being outwardly accessible through a spring cavity access opening (502).

7. A needle guard (2) as in claim 6 wherein the spring (104) is a compression spring that is in contact with the locking plate (102).

8. A needle guard (2) as in claim 6 wherein the alignment means comprises a lever arm (101) and the spring is a torsional spring (544) that is in contact with said lever arm (101).

5 9. A needle guard (2) as in claim 6 wherein the spring cavity access opening (502) is located on the same side of the body (106) as the needle-access opening (501).

10. A needle guard (2) as in claim 6 wherein the spring cavity access opening (502) is located on other than the same
10 side of body (106) as the needle-access opening (501).

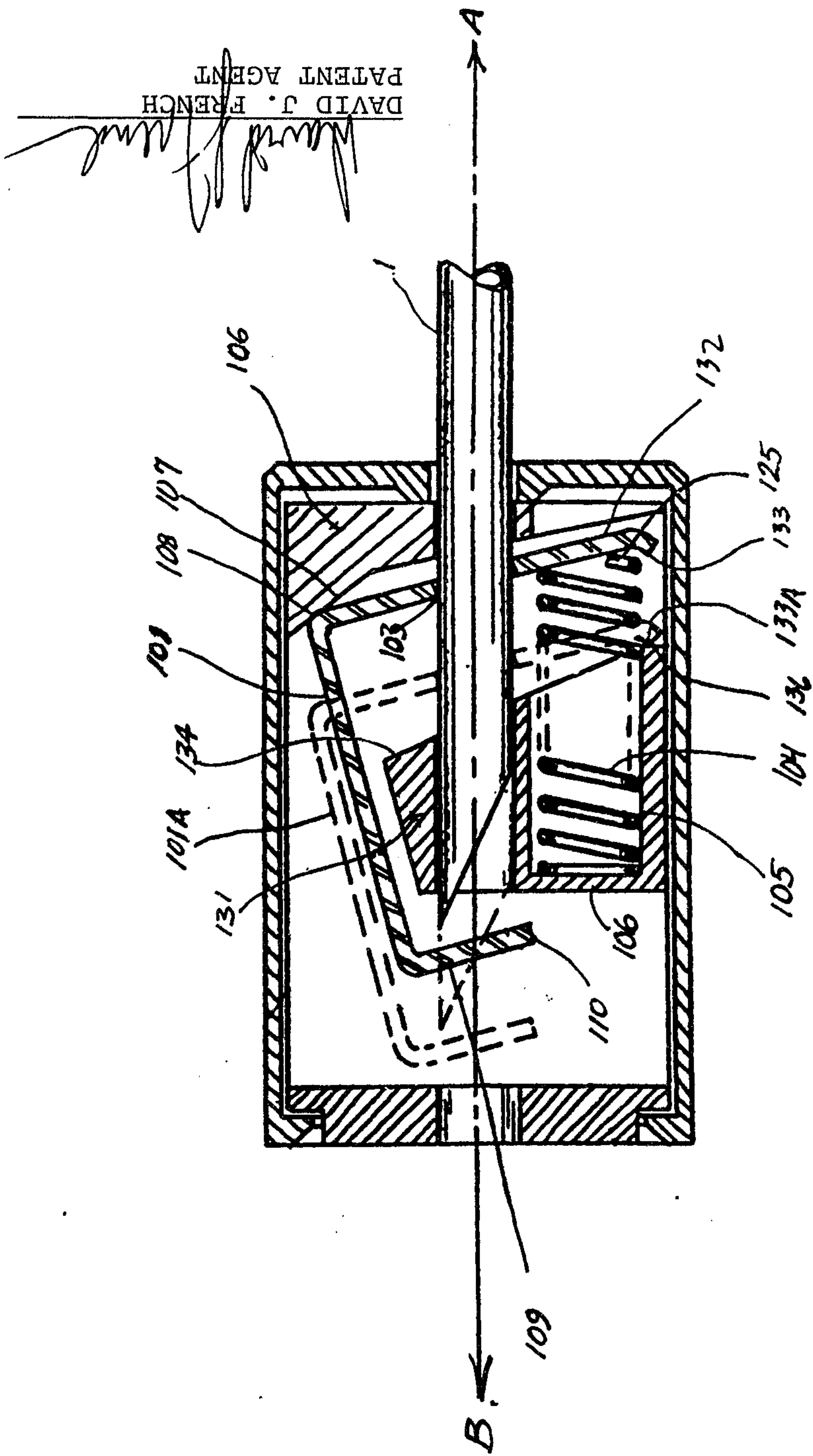
11. A needle guard (2) as in claims 6 wherein the spring cavity access opening (501) is undercut to a width that will allow the spring (104) to be inserted therein under pressure, but will retain the spring (104) within the spring cavity
15 (105) thereafter.

12. A needle guard (2) as in claim 3 wherein the lever arm (101) comprises a laterally displaced longitudinal bar (103A) the plane of rotation of which is laterally displaced from the inner needle passageway (511) of the body (106).

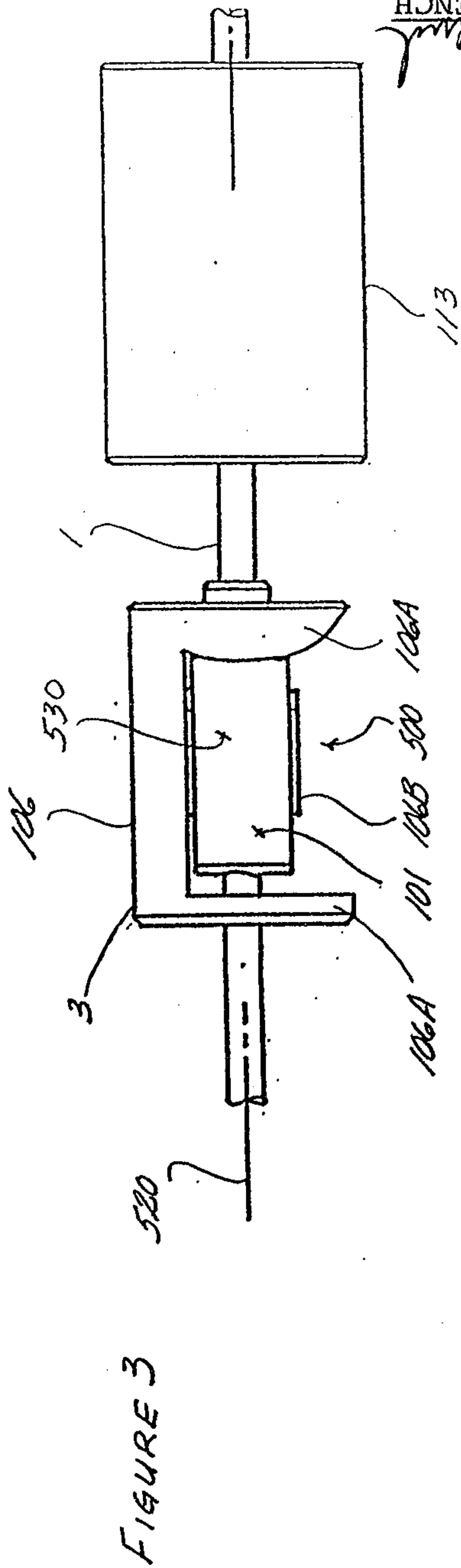
20 13. A needle guard (2) as in claim 3, 4 or 12 wherein the lever arm (101) terminates at its second end with a blocking plate portion (521) which is biased by the spring (104) to pass into the axial path of the needle (1) when the

needle tip (4) is drawn past the needle sensing end (110) of the lever arm (101).

14. A needle guard in combination with a catheter assembly including a catheter with a base and an insertion
5 needle with a tip and a base end, said needle initially penetrating through said base and catheter, wherein said needle guard is initially mounted on such needle adjacent said base end for subsequent movement to a tip-covering position along the needle when the insertion needle is removed from the
10 catheter, said needle guard comprising:
- (a) coupling means carried by the needle guard to releasably couple the needle guard to the base of the catheter until the needle guard is deployed at a tip-covering position;
 - 15 (b) access means within the needle guard whereby the needle guard may be mounted on the needle from a lateral position; and
 - (c) needle engagement means within said needle guard for engaging the needle guard to the needle in a tip-
20 covering position when the needle tip is withdrawn from the base of the catheter.



~ FIG. 2 ~



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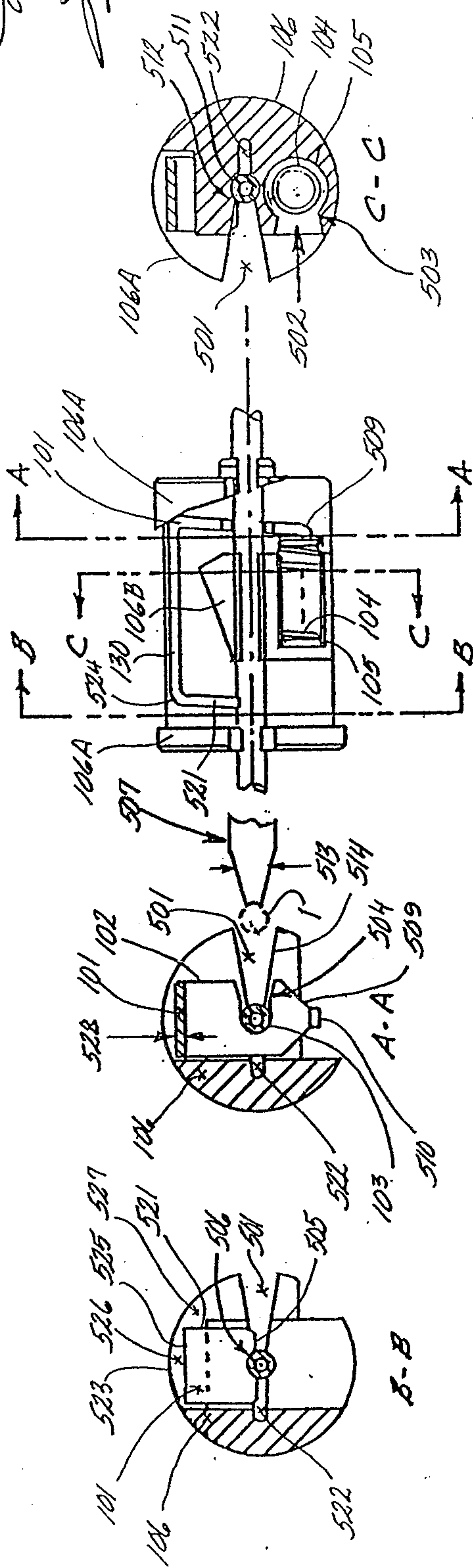
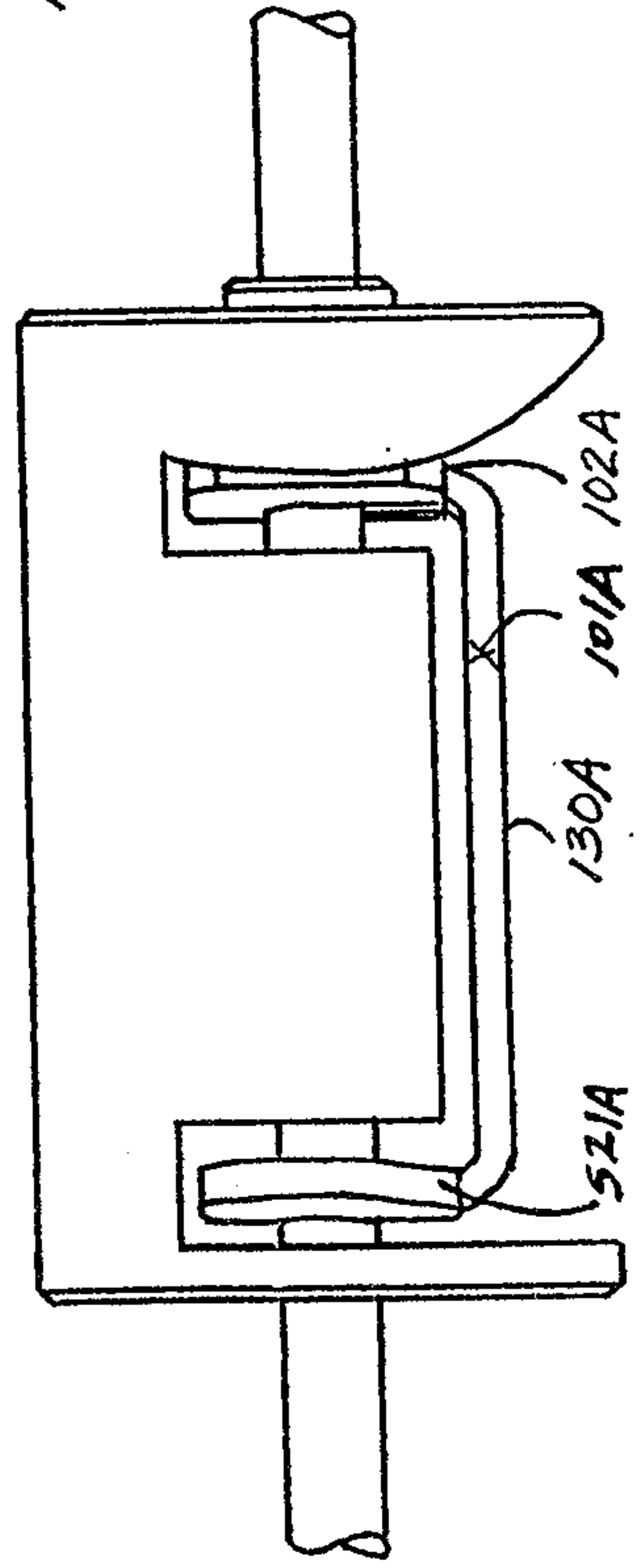


FIGURE 5



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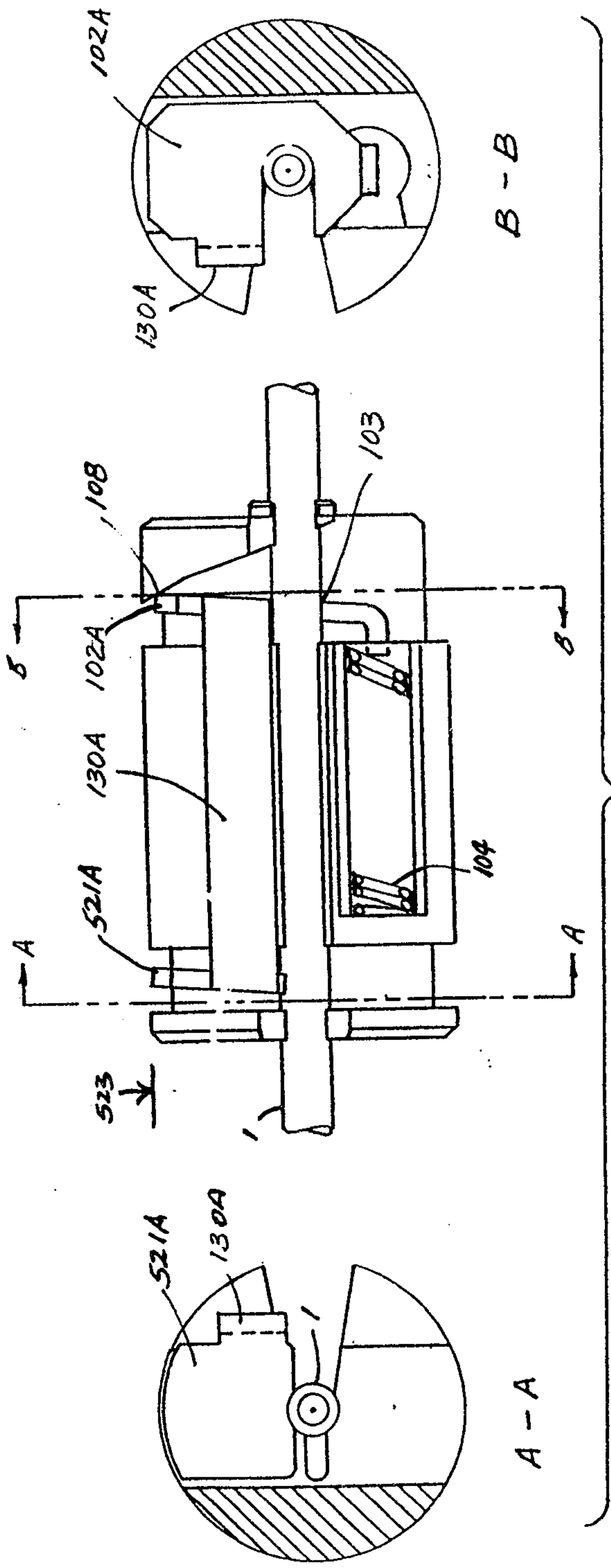
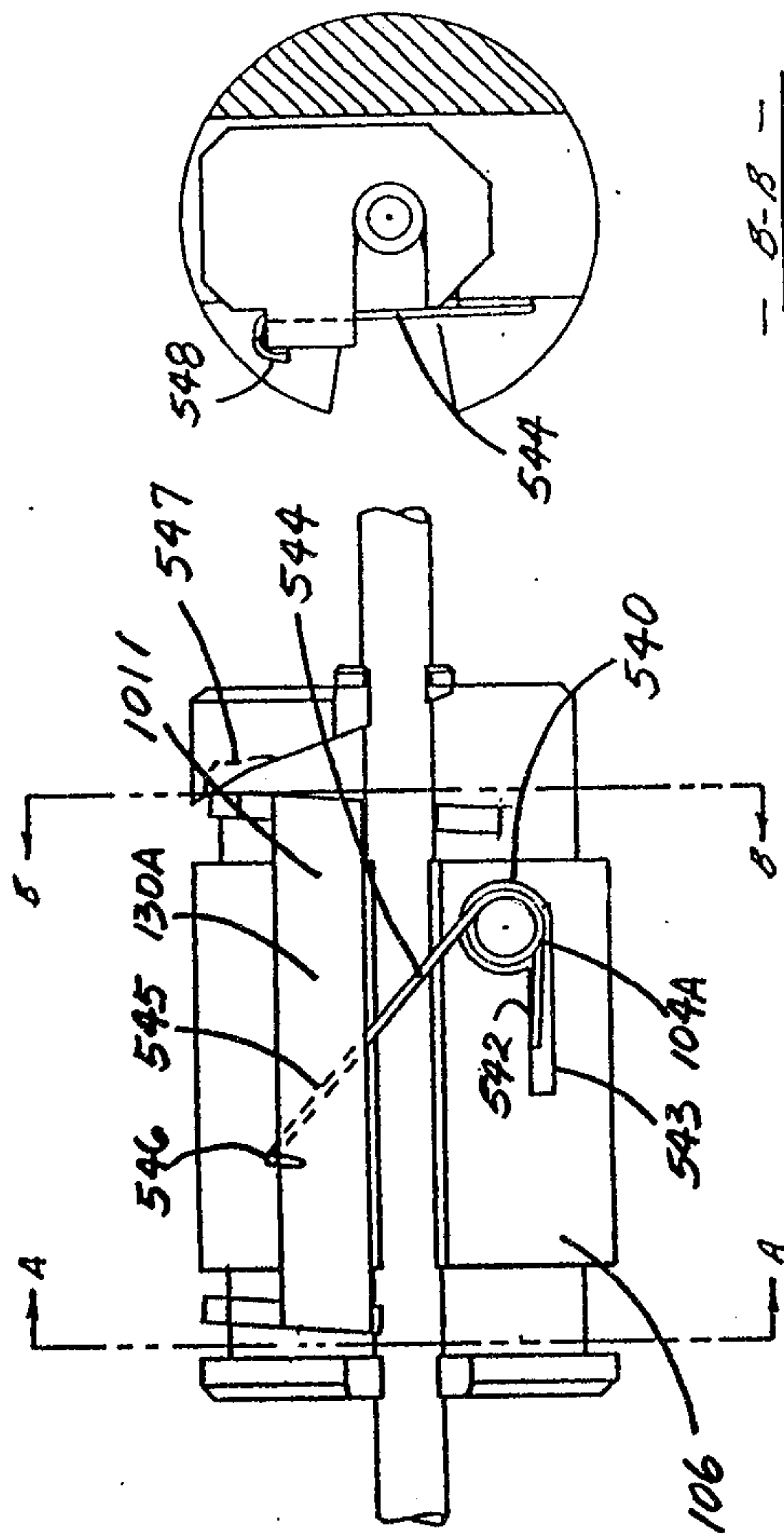
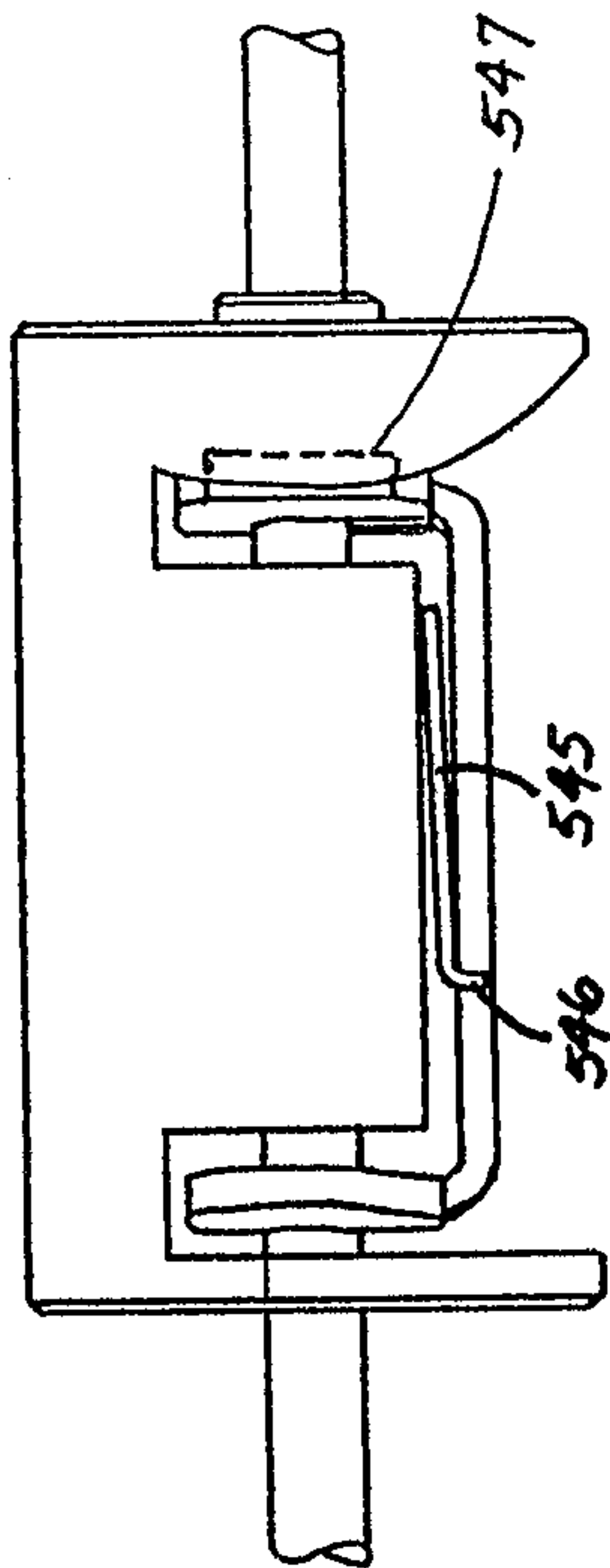


FIGURE 6

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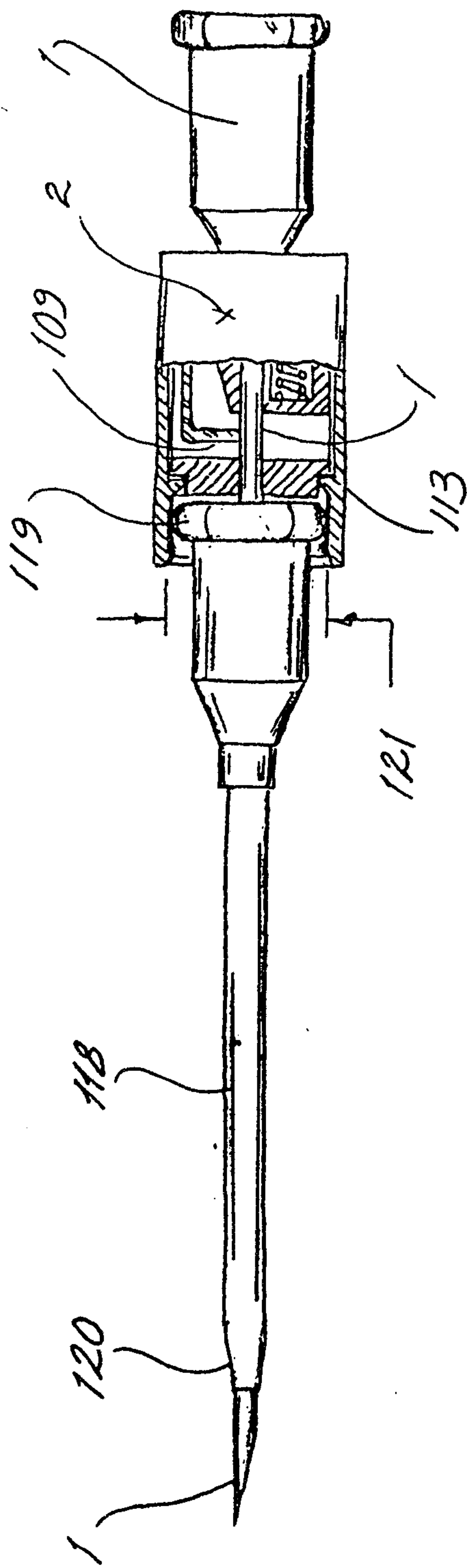
FIGURE 7



-A-A-

8-8 -

FIGURE 8



~ FIG. 9 ~

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