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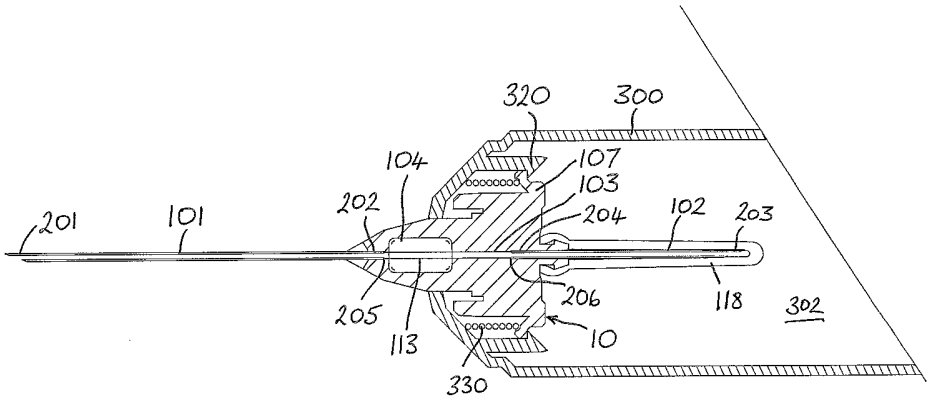
(54) **Title:** A NEEDLE ASSEMBLY FOR A BODY FLUIDS SAMPLING DEVICE




(57) **Abstract:** First and second hollow needles (101, 102) extend from opposing sides of a common hub (107). Proximal ends (202, 204) of the respective needles (101, 102) are in communication with each other by a narrow passageway (103, 113) through the hub (107) which is formed in one piece and of transparent material. The hub (107) preferably includes a magnifying formation overlying the passageway portion (113) between the proximal ends of the needles (101, 102). As shown, the device (10) may be mounted in a front end of a tubular holder, such as a syringe body (30). In other versions the needles (101, 102) may be offset but parallel to one another (Fig. 2) or the principal ayes of the needles may intersect at an angle of between 1 ° and 45° (Fig. 4 and 5).

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# A NEEDLE ASSEMBLY FOR A BODY FLUIDS SAMPLING DEVICE

## TECHNICAL FIELD OF THE INVENTION

This invention concerns a needle assembly for a body fluid (particularly blood) sampling device.

## BACKGROUND ART

Conventional blood samplers comprise a hollow needle mounted in and extending through a hub, by means of which the device may be held by a user and optionally mounted within a syringe body or the like. The needle is of stainless steel and has a sharp point at each end. One end is intended for insertion into a patient's vein. The other end is designed for insertion into a pre-evacuated collection tube, its sharp point being necessary to pierce a sealed septum of the collection tube. With the first end appropriately inserted into a vein, blood is sucked into the collection tube by vacuum as soon as the septum is pierced. Multiple blood samples may be taken successively from the same patient via the same needle into a succession of pre-evacuated collection tubes. When the required number of samples have been collected, the needle is withdrawn from the vein and the sampler is either discarded, or alternatively, if the sampler is mounted in a syringe body as described in our earlier patent specification EP-A-0648136, it is automatically retracted under spring bias into the syringe body.

There is one serious problem with conventional blood sampling devices. The user cannot be sure that the needle tip is appropriately located in a patient's vein until after the pre-evacuated collection tube has been applied to the other end and blood is seen to be entering the tube. If the needle tip is not in the vein, the vacuum will suck in tissue, which can be painful for the patient and lead to significant bruising, and the collection tube, which is relatively expensive, will be wasted as its septum has been pierced. The patient has to suffer a further attempt to locate a vein and time is wasted.

In US4,679,571 a proposal has been made for overcoming this problem by providing two separate needles, one for insertion into the patient's vein and one for connection to an evacuated container, which are mounted to opposing sides of a housing. The housing provides a passageway between the two needles and has a chamber therein with transparent walls through which the presence or absence of a blood sample will be visually apparent. The housing is formed of two parts which fit together so that one projects into the other and an annular space is defined between the parts which provides the chamber for viewing the presence of a sample. A relatively large initial volume of any sample is bled off into the annular chamber, and this can only be accomplished by venting air from the chamber.

In order to visualise the sample in the chamber and also as a measure to seal off the chamber to prevent leaking a swellable tablet or sleeve of a proprietary starch graft co-polymer is proposed to be located in the chamber. Obviously such a needle assembly is complex and would be expensive to produce and is fraught with possibilities for malfunction. Current health regulations preclude any possibility of leakage from a device used for taking blood samples, so any device requiring venting from a visualisation or 'flash' chamber is impractical.

Another proposal for indicating when a needle has entered a patient's vein is made in US5,137,518. This proposal involves use of a fibre optic mounted in the needle and extending to a transparent hub which is formed with surfaces which provide for magnification and reflection of the light transmitted from the distal end of the needle. Such a device is not believed to be commercially practical.

Other proposals have been made, but all involve complex multi-part assemblies which do not preclude leakage of the sampled fluid.

## OBJECT OF THE INVENTION

An object of the invention is to overcome all the aforesaid problems and provide a cost-effective needle assembly for a body fluid sampling device which will, without any risk of leakage, provide a reliable visual indication that the needle tip is correctly located in a vein before a pre-evacuated collection tube is applied.

## SUMMARY OF THE INVENTION

This object is achieved by providing a needle assembly for a body fluids sampling device which comprises first and second hollow needles extending from opposing sides of a common hub, the proximal ends of the respective needles being in communication with each other by a passageway through the hub which is provided with a transparent window, whereby the passageway is visible, characterised in that the hub is formed in one piece and of transparent material.

In use, a patient's blood pressure will be sufficient to force some blood into the hollow needle used to pierce the vein and into the connecting duct between the proximal ends of the respective needles, where it can be viewed through the surrounding transparent material. In this respect, the passageway or duct between the proximal ends of the respective needles is kept as short and as narrow as is feasible. As needles conventionally used in blood sampling devices may have an outer diameter (OD) of about 0.9 to 1.0mm, the passageway between the needle ends may be as little as 0.8mm wide in many embodiments of the present invention. Only the end sections of the passageway where end regions of the needles are accommodated need to be equal to the OD of the needles. Air displaced from the passageway as blood flows in will pass out of the second needle and any cover thereover will be sufficiently elastic to allow for this. Thus, in accordance with the invention there is no intermediate chamber to which blood must pass in order to be observed and no requirement for venting such chamber. Indeed, there is no possibility of leakage because of the one piece hub formation.

Obviously, the needle assembly of the invention (also referred to herein as a sampler device) is not limited to blood sampling, although that is likely to be its primarily application, and could be used or adapted for use in sampling other body fluids of human or animal origin.

Advantageously at least part of the visible passageway between the proximal ends of the needles is magnified so that a user may more easily witness introduction of blood or other body fluid into said passageway. Thus, a magnifying formation acting as a magnifying lens preferably overlies at least part of the passageway.

Because this invention requires two separate needles, it permits another advantageous development, namely the displacement of one of the two needles out of alignment with the axis of the other of the two needles.

In practice, the needle intended to enter the patient's vein may be offset from the axis of the device, whereas the needle intended to enter the collection tube will need to remain in an axial disposition so as to pierce the septum of the collection tube centrally, at its weakest position, as the hub fits into the neck of the tube.

Such an offset disposition for the patient piercing needle has the advantage of allowing a lower angle of entry into the patient. This makes it easier to locate the needle tip into a vein without piercing the other (inner) wall of the vein, which is often a difficult task, particularly in very young, elderly or overweight patients.

Essentially, there are three possibilities for such an offset disposition. First, the first and second needles have principal axes that are parallel to one another. Second, the first and second needles have their proximal ends substantially in alignment but one of the needles extends at an oblique angle relative to the other so that the principal axes of the respective needles do not coincide. The third possibility is that the proximal ends of the first and second needles are offset as well as one needle

extending at an oblique angle relative to the other. That angle in either the second or third possible arrangement may be from $135^0$ to $179^0$. In other words the principal axes of the first and second hollow needles intersect at an angle of between 1° and 45°.

## BRIEF DESCRIPTION OF DRAWINGS

The invention will be described further, by way of example, with reference to the accompanying drawings, in which:

Fig. 1 is a fragmentary longitudinal cross-section of a first practical embodiment of a needle assembly according to the present invention when mounted into a syringe body with needle retraction provision;

Fig. 2 is a side elevation of a second practical embodiment of a needle assembly (sampler device) according to the invention;

Fig. 3 is a fragmentary, reduced scale partially sectional side view showing the device of Fig. 2 mounted into a syringe body with needle retraction provision in an "in use" position;

Fig. 4 is a side elevation, similar to Fig. 2, of a third practical embodiment of a needle assembly according to the present invention; and

Fig. 5 is a side elevation, also similar to Fig. 2, of a fourth practical embodiment of a needle assembly according to the present invention.

## DETAILED DESCRIPTION OF ILLUSTRATED EMBODIMENTS

Referring to Fig. 1, a first embodiment of the invention is an in-line witnessing multi-sample needle assembly 10. It comprises a first hollow hypodermic needle 101, a second hollow hypodermic needle 102, a hub 107 and a soft flexible cover 118 over

the second needle 102. The first and second needles 101, 102 extend from opposed ends of the hub 107 in alignment with each other, i.e. co-incident axes.

Both of the needles 101, 102 are necessarily of stainless steel or comparable material to meet required standards for medical devices.

The first needle 101 has, at one end, a multi-ground point 201 for penetration of a patients' skin and vein wall, while its other end 202 is plain and is bonded to the hub 107. The second needle 102 also has a ground point 203 at its free end, which is for piercing of a septum of a pre-evacuated blood sampling tube (not shown). The cover 118 would also be pierced in that operation. The other end 204 of the second needle 102 is also plain and is also bonded to the hub 107.

The hub 107 is formed in one piece of crystal clear (ie transparent) thermoplastic resin, such as a polycarbonate or ABS resin. A linear passageway 103 is formed through the hub 107. The end regions at the plain ends 202, 204 of the respective needles 101, 201 extend a short distance into opposing wider end sections of the passageway 103 up to respective locating shoulders 205, 206 which limit the insertion of the respective needle ends 202, 204 during manufacture of the device. The respective end regions of the needles 101, 201 are securely bonded in the end sections of the passageway 103 by any suitable adhesive.

A gap remains between the shoulders 205, 206 and therefore between the needle ends 202, 204. This gap provided by a central section 113 of the passageway 103, enables fluid, particularly blood, flowing into the passageway 103 to be seen by a user of the device through the transparent hub material.

A convex magnifying formation 104 is provided as an integral part of the exterior surface of the hub 107 overlying the central section 113 of the passageway 103 between the ends 202, 204 of the needles 101, 102. This magnifying formation acts as a lens and enlarges the view of this passageway section 113. In practise, the

convex formation 104 may be sunk into a recess in the exterior of the hub 107 so that the hub exterior remains generally symmetrical and is still able to fit with minimum clearance into a holder, such as a syringe body 300.

The passageway 103 through the hub 107 needs, in its end sections, to match the OD of the needles 101, 102, which is typically 0.9 to 1.0mm in order to accommodate the end regions of same. The central section 113 of the passageway 103, between the shoulders 205, 206, which delimit the position of the needles, is narrower and may be about 0.8mm.

In use, when the end 201 of the first needle 101 is correctly inserted into a vein of a patient, his/her blood pressure will be sufficient to force blood through the first needle 101 and into the central section 113 of the passageway 103. This blood will be visible in the central section 113 of the passageway 103, as viewed via the magnifying formation 104. Air displaced by the blood coming up into the passageway 103 will pass out of the end 203 of the second needle 102 and the cover 118 is sufficiently elastic/flexible to accommodate the small volume of air expelled.

The sampler assembly 10 is shown mounted into a syringe body 300 of known type which has a single interior chamber 302 and latching provisions 320 in a front end of this chamber 302 for retaining the hub 107 against the bias of a spring 330. These latching provisions 320 are deflectable outwards eg. by insertion of a hollow plunger (not shown) into the body 300 to release the spring 330 and retract the needle assembly 10, including the full extent of the first needle 101 into the chamber 302 and into the plunger, in a manner disclosed in the applicant's earlier EP-A-0648136.

The configuration of the hub 107 and the size of the opening in the front end of the syringe body 300 are such, in this embodiment, that a portion of the hub 107, including at least a portion of the magnifying formation 104, extend from the front end of the syringe body 300. This is to ensure clear visibility of the passageway 113, and witnessing of entry of blood when a vein is pierced, via the transparent hub

material and the magnifying formation 104. Although the syringe body 300 will generally be formed of transparent material, such as transparent polypropylene, the visibility of the passageway section 113 may nevertheless be somewhat blurred if it has to be viewed through both the body 300 and the hub 107. Projection of part of the hub 107 out of the body 300 in this design avoids this potential problem. However, in other embodiments, substantially all of the hub 107, including all of the magnifier formation 104, may be located inside a transparent syringe body 300 with acceptable visibility of the witnessing duct 113.

Referring now to Figs. 2 and 3 a second embodiment of the invention is an offset witnessing multi-sample needle assembly 20. The same reference numerals are used to designate parts which correspond to those of the first embodiment and these will not be described again.

The proximal ends 202, 204 of the needles 101, 102 are in this embodiment located and bonded into axially offset portions 108, 109 of the passageway through the transparent hub 107. The needles 101, 102 have principle axes extending parallel to one other. As best shown in Fig. 3 the second needle 102 is still axial of the device and the syringe body 310 in which it can be mounted, whereas the first needle 101 is now offset from that axis.

The passageway through the hub 107 consists of the aforesaid axially offset portions 108, 109, which lie substantially parallel to each other but extend in from opposing sides of the hub, and a transverse bridging portion 105 which connects these two offset portions 108, 109. The offset portions 108, 109 of the passageway are formed as blind bores from opposing sides of the hub 107. Each has a narrower inner end region delimited by a respective shoulder 208, 209 which serves to limit insertion of the proximal ends 202, 204 of the respective needles 101, 102 during manufacture. The needles 101, 102 are bonded to the hub 107 once inserted. The bridging portion 105 of the passageway extends between and substantially perpendicular to the narrower inner end regions of the offset portions 108, 109 of the passageway.

The hub 107 is manufactured in one piece by injection moulding and the bridging portion 105 is formed during moulding by use of a sliding core. When the core is withdrawn the bridging portion 105 initially extends to, i.e. is open to, the outside of the hub 107. The open end may be sealed off by a plug 106, which may suitably be formed of polypropylene and may be a simple push fit therein. However, a more reliable leak proof closure to the bridging portion 105 may be achieved by shaping the mould for the hub 107 to provide additional material encircling the point of entry and exit of the sliding core. After the bridging portion 105 has been formed its open end is then closed off by a tool which softens the surrounding mound of material and pushes it into the open end.

Again the outer sections of the passageway through the hub 107 need to match the OD of the needles 101, 102 which they accommodate. The narrower inner ends of the blind bores 108, 109 may be of a diameter as little as 0.8mm. The bridging portion 105 of the passageway may need to be of slightly larger diameter, such as 1.0mm to 1.5mm, owing to manufacturing constraints.

By use of this axially offset arrangement of needles the angle of attack (a) at the skin 400 of a patient (Fig. 3) can be reduced from a minimum of $16^0$ as for existing single needle samplers or the in-line sampler 10 to a minimum of $4^0$.

Obviously the syringe body 310 must be appropriately provided with a non-axial opening at a suitable position for projection therethrough of the needle 101 and at least a small portion of the hub 107 where the passageway portion 108 is formed.

In other respects, this embodiment is used in exactly the same way as described for the first embodiment of Fig. 1.

Fig. 4 shows a third embodiment 30 of the device of the invention which is akin to the first embodiment (Fig.1). The same reference numerals are used for

corresponding parts and these need not be described again. It differs from the first embodiment in that instead of a single linear passageway through the hub the passageway 103 is formed by respective blind bores 112, 114 which intersect at an angle of between 1° and 45°, preferably about 20° to 30°. In this respect, the bore 114, into which the needle 102 for insertion into the collection vessel is located, is axial, while the other bore 112, into which the needle 101 for piercing the vein is located, extends at an angle thereto. Thus, the through passageway 103 itself bends at an obtuse angle of between 135° and 179° (preferably 150° and 160°) and there are two blind ends of short extent. The intersection of the bores 112, 114 is generally in the middle of the hub 107 and is overlain by a magnifying formation 104 for witnessing of blood entry into the needle 101 as before.

Fig. 5 shows a fourth embodiment 40 which bears resemblance to the embodiment of Figs. 2 and 3 in that the passageway through the hub 107 is formed by two blind bores 116, 117 extending from opposing sides of the hub and connected by a transverse bridging portion 115. However, it is also similar to the preceding embodiment in that the blind bore 117 is axial of the hub 107, while the blind bore 116 is both offset by a short spacing and also extends at an angle of between 1° and 45° (preferably 20° and 30°) to the axis of the hub 107.

Both the aforesaid embodiments (Figs. 4 and 5), in use, enable a reduced angle of attack at the skin of a patient.

The foregoing is illustrative not limitative of the scope of the invention. Many variations in detail are possible in other embodiments.

## CLAIMS

1. A needle assembly for a body fluids sampling device comprising first and second hollow needles extending from opposing sides of a common hub, the proximal ends of the respective needles being in communication with each other by a passageway through the hub which is provided with a transparent window whereby the passageway is visible, characterised in that the hub is formed in one piece and of transparent material.

2. A needle assembly according to claim 1 wherein the hub includes a magnifying formation overlying the passageway between the proximal ends of the needles.

3. A needle assembly according to claim 1 or 2 wherein the passageway through the hub has wider end sections delimited by steps and proximal end regions of the respective needles are located and bonded in these wider end sections.

4. A needle assembly according to any of claims 1, 2 or 3 wherein the hollow needles are linear and have principle axes that do not coincide.

5. A needle assembly according to claim 4 wherein the needles are parallel to one another.

6. A needle assembly according to claim 4 wherein the proximal ends of the respective needles are offset from each other.

7. A needle assembly according to claim 4 or 6 wherein the principal axes of the first and second hollow needles intersect at an angle of between 1° and $45^0$.

8. A needle assembly according to any preceding claim wherein the passageway has respective axially offset sections, into which the proximal end regions of

the first and second needles are mounted, and a bridging section which extends transversely between these axially offset sections.

9. A needle assembly according to claim 8 wherein the bridging section extends beyond at least one of the axially offset sections of the passageway towards the outside of the hub where it is closed off.

10. A body fluids sampling device comprising a substantially tubular holder body in combination with a needle assembly according to any of claims 1 to 9, in which respect the holder body has a single interior chamber, which serves for reception of a sampling vial, and the hub of the needle assembly is located in a front end of said single interior chamber of the holder body such that the first hollow needle extends from the front end of the body and the second hollow needle extends into said single interior chamber thereof.

11. A body fluids sampling device comprising a substantially tubular holder body in combination with a needle assembly according to claim 2, in which respect the holder body has an interior chamber for reception of a sampling vial and the hub of the needle assembly is located in a front end of said interior chamber of the holder body such that a portion of the hub including at least a portion of the magnifying formation as well as the first hollow needle extends from the front end of the body while the second hollow needle extends into the interior chamber thereof.

12. A needle assembly for a body fluids sampling device substantially as hereinbefore described with reference to and as illustrated by Fig. 1 or Figs. 2 and 3, or Fig 4, or Fig. 5 of the accompanying drawings.

13. A body fluids sampling device substantially as hereinbefore described with reference to and as illustrated by Fig. 1 or Fig. 3 of the accompanying drawings.

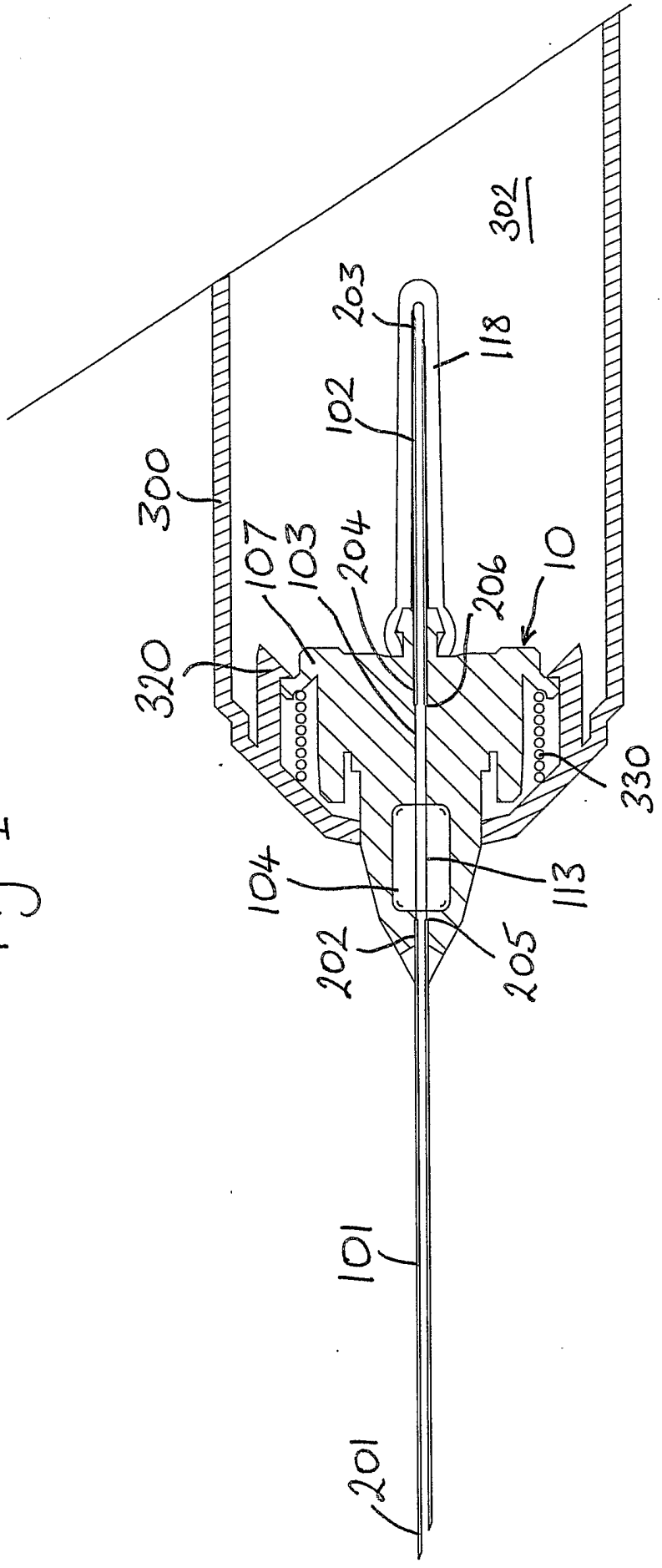
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Fig. 1

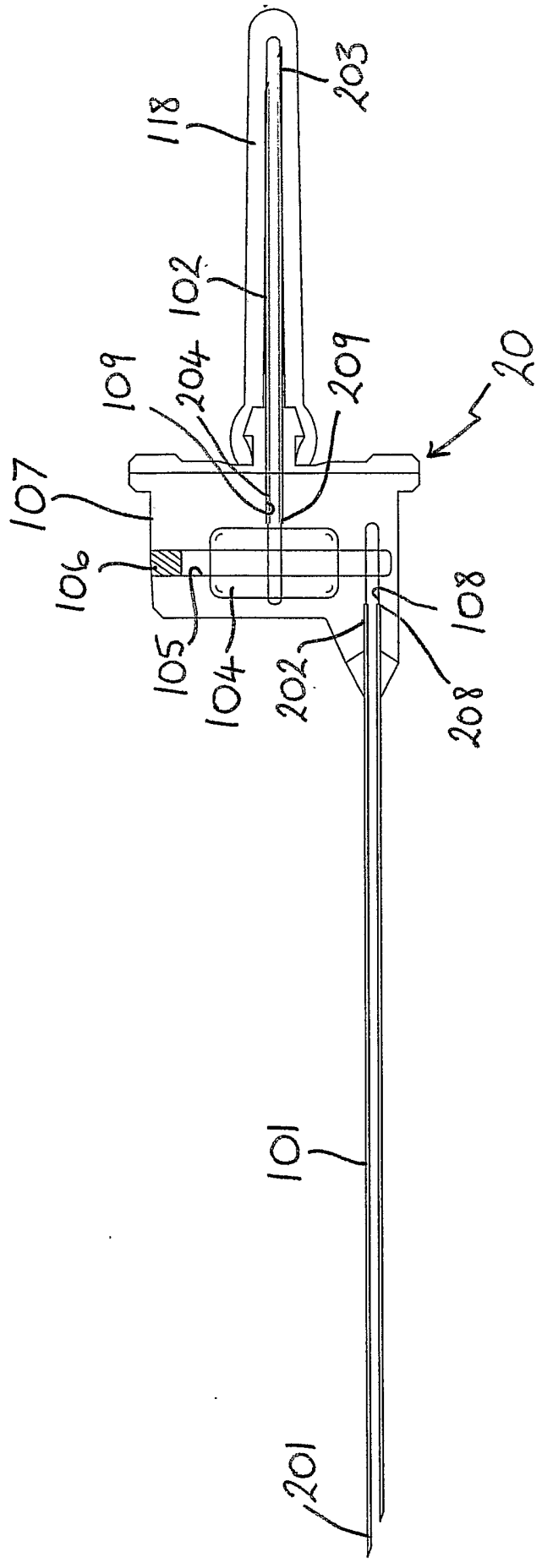


Fig. 2

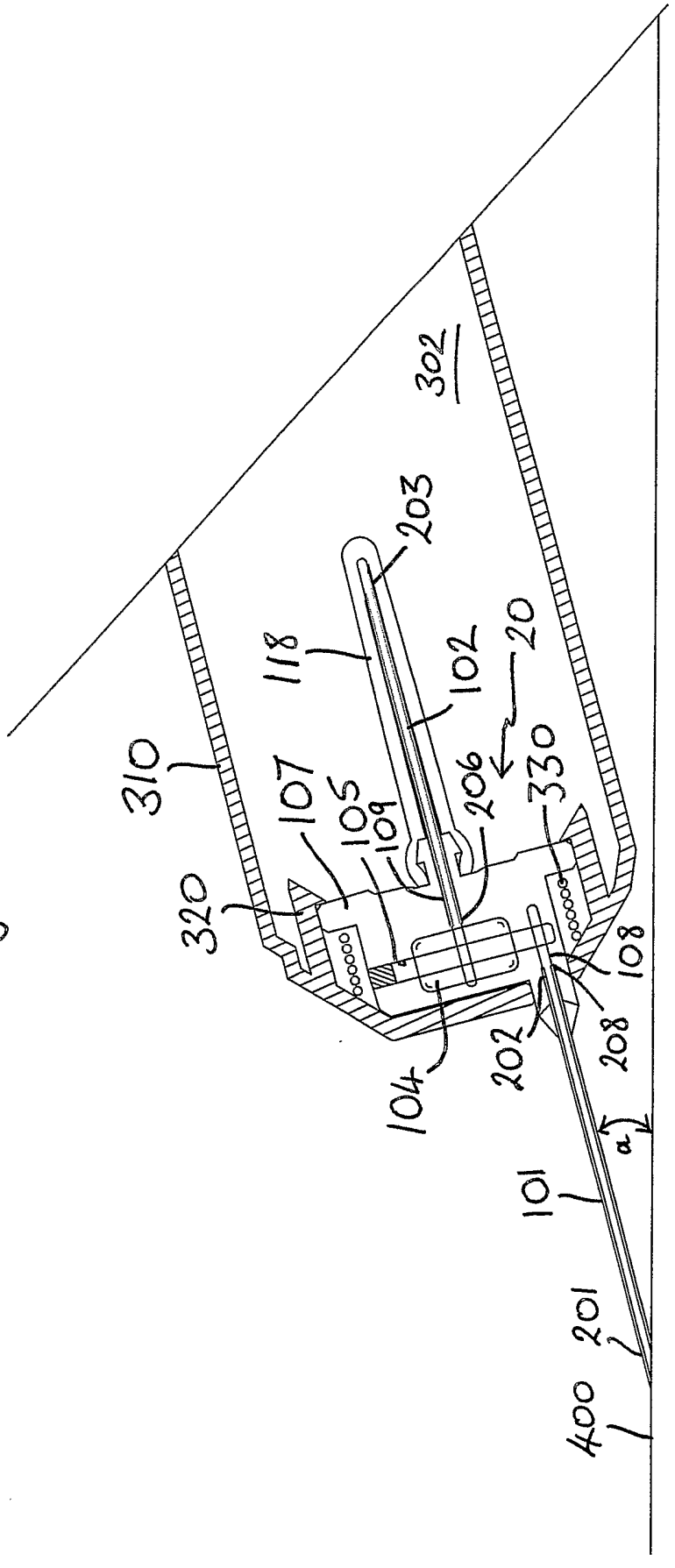
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Fig. 3

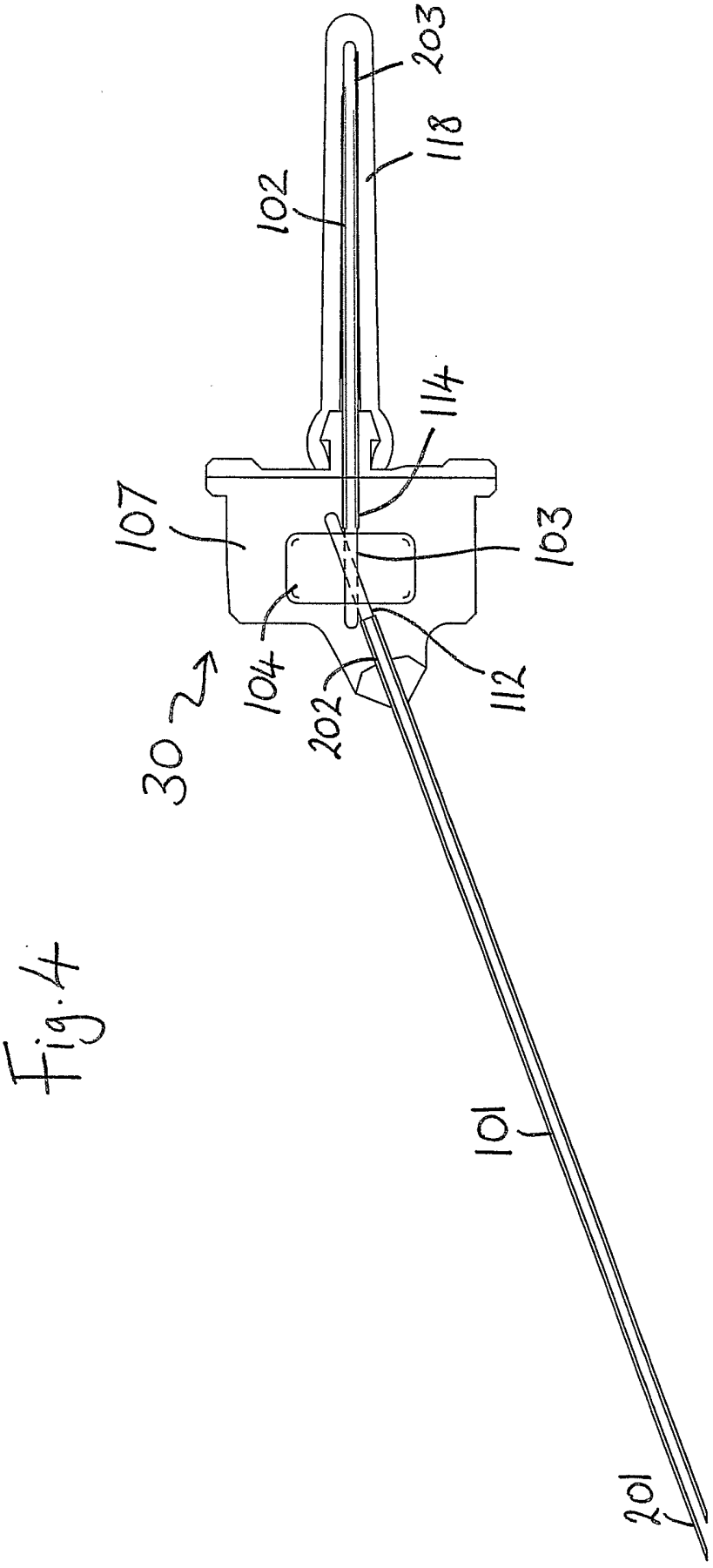


Fig. 4

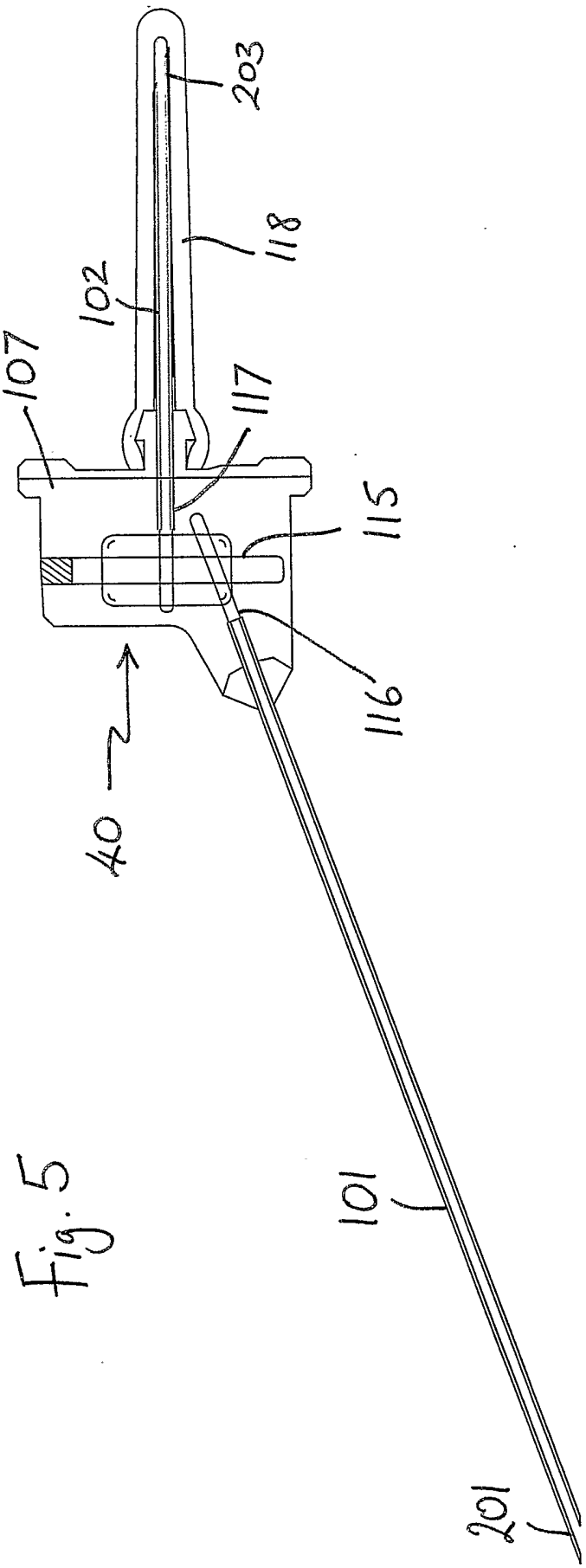


Fig. 5

# INTERNATIONAL SEARCH REPORT

International Application No
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A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B5/00 A61M25/06 A61B10/00 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 7 A61M A61B A61N

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)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category ° | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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| Date of the actual completion of the international search | Date of mailing of the international search report |
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| 21 June 2005 | 29/06/2005 |

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| European Patent Office, P.B. 5818 Patentlaan 2<br>NL – 2280 HV Rijswijk<br>Tel. (+31–70) 340–2040, Tx. 31 651 epo nl,<br>Fax: (+31–70) 340–3016 | Reinbold, S |

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

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