



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification³ : A61B 10/00	A1	(11) International Publication Number: WO 83/ 03343 (43) International Publication Date: 13 October 1983 (13.10.83)
(21) International Application Number: PCT/SE83/00112 (22) International Filing Date: 28 March 1983 (28.03.83) (31) Priority Application Number: 8202061-1 (32) Priority Date: 31 March 1982 (31.03.82) (33) Priority Country: SE (71) Applicant (for all designated States except US): RADI-PLAST AB [SE/SE]; Karlsrogatan 46, S-752 39 Uppsala (SE). (72) Inventors; and (75) Inventors/Applicants (for US only) : ALLARD, Jan, Håkan [SE/SE]; Nyåkersgatan 8, S-733 00 Sala (SE). LINDGREN, Per, Gunnar [SE/SE]; Gråbersvägen 24A, S-752 40 Uppsala (SE). (81) Designated States: AT (European patent), AU, BE (European patent), CH (European patent), DE (European patent), DK, FI, FR (European patent), GB (European patent), JP, LU (European patent), NL (European patent), NO, US.		Published <i>With international search report.</i> <i>In English translation (filed in Swedish).</i>
(54) Title: A DEVICE FOR TAKING TISSUE SAMPLES (57) Abstract A device for tissue sampling by means of so-called puncture, i.e. by piercing of the skin from the outside by means of a needle unit, which is inserted to the sampling place at which a tissue sample is taken, which sampling can take place under surveillance by ultrasonic equipment, the needle unit consisting of an independently actuatable hollow outer needle (2) and an independently actuatable inner needle having a reduced portion close to its point for accommodating tissue samples after the tissue sampling has been performed. The device (1) consists of a unit in which the needle unit can be placed, a driving means for propelling the inner needle, a driving means for propelling the outer needle (2), and triggering means (12) for said driving means. The device comprises a casing or a box, in which the needle unit can be placed, a cover which can be opened and closed, as well as bottom piece.		

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	LI	Liechtenstein
AU	Australia	LK	Sri Lanka
BE	Belgium	LU	Luxembourg
BR	Brazil	MC	Monaco
CF	Central African Republic	MG	Madagascar
CG	Congo	MR	Mauritania
CH	Switzerland	MW	Malawi
CM	Cameroon	NL	Netherlands
DE	Germany, Federal Republic of	NO	Norway
DK	Denmark	RO	Romania
FI	Finland	SE	Sweden
FR	France	SN	Senegal
GA	Gabon	SU	Soviet Union
GB	United Kingdom	TD	Chad
HU	Hungary	TG	Togo
JP	Japan	US	United States of America
KP	Democratic People's Republic of Korea		

A DEVICE FOR TAKING TISSUE SAMPLES.TECHNICAL FIELD

The present invention relates to a device for taking tissue samples, and the invention more specifically relates to a device for facilitating and making possible for one person to take samples of tissue located inside the human body, such as from the kidney and liver, if pathological changes are suspected. The location at which the sampling is to take place is best determined by means of ultrasonic equipment. The sampling which is carried out as puncture, i.e. piercing of the skin from the outside with a hollow needle which can be inserted to the location of the sampling where a tissue sample is taken, can be carried out under surveillance by the ultrasonic equipment.

BACKGROUND OF THE INVENTION

Tissue sampling using so-called coarse needle puncture has become increasingly common. Tissue samples which have been taken can be analyzed in various ways, for example by means of a microscope or chemically. The sampling is carried out such that one doctor performs the very puncture and another doctor assists by operating the ultrasonic equipment used in order to localize the place of the sampling and to control that the tissue sample is taken from the correct place. The doctor who carries out the puncture depresses a hollow needle from the exterior through the skin and to the intended sampling place, which is thus determined by the ultrasonic equipment, where tissue samples are taken. This is done by depressing an inner needle, which is located inside the hollow needle, a short distance further into the tissue from which it is desired to take a sample. This inner needle has a pointed front part, which further has a reduced portion near the point. The tissue expands into this portion, whereupon the outer hollow needle is applied, by which a tissue sample is cut out and accommodated in the reduced portion inside the front part of the inner needle. Thereafter the entire needle unit can be withdrawn, whereupon the tissue sample can be analyzed in various ways, for example microscopically or chemically.

Although this method of performing tissue sampling is very elegant and not painful to the patient, it is realized that it is necessary, for performing the puncture properly, for two doctors to take part in the work, of which as mentioned above one doctor attends to the ultrasonic equipment for localizing the sampling place and controls that the sampling is made at the correct place, and the other doctor performs the very puncture, which necessarily requires manipulation with both hands since the handling of the inner needle is carried out with one hand and the handling of the outer needle part with the other.



Further, it has been found that the very sampling procedure must be carried out with great skill and precision since it very easily can happen that the inner needle, after having been inserted into the correct place, unintentionally is withdrawn outwards and into the outer needle instead of the outer needle being brought forward and around the inner needle. On correct handling, i.e. when first the entire needle unit is inserted to the correct place, the inner needle then is brought forward and finally the outer needle is brought to move forwards and around the inner needle, a shearing action takes place, whereby a sufficient amount of tissue sample is sheared off by the forward motion of the outer needle, which tissue sample then will be located in the space present between the front part of the inner needle and the outer needle. If instead thereof, by mistake, the inner needle is withdrawn into the outer needle, something which can happen very easily, then only a scratch-like action takes place, in which hardly any or at least an insufficient amount of tissue sample will be accommodated in the area intended therefor between the needles.

THE OBJECT OF THE INVENTION

This invention aims at providing a device for use in connection with tissue sampling by means of puncture of the kind indicated above, wherein the previous drawback that two doctors have to take part in the sampling can be eliminated by means of a device according to the invention, which makes possible one-man controlled tissue sampling by means of puncture. This can be achieved by means of a device according to the invention, and the tissue sampling is in accordance with the invention carried out in a manner such that the doctor handles and controls the ultrasonic equipment with his one hand for localization and surveillance, while at the same time the same doctor with his other hand performs the very puncture by inserting the needle unit such that its point will be at the correct sampling place, whereupon the doctor with the same hand triggers an automatic sampling operation, by means of which the inner needle is at first expelled a desired extent and the outer needle then automatically triggered, whereby the tissue sampling takes place. Thereafter the doctor can withdraw the needle unit, and the tissue sampling is finished.

The invention further aims at eliminating the above cited drawback as to the very handling procedure, viz. the risk of withdrawing, by mistake, the inner needle instead of expelling the outer needle at the very sampling moment. This risk is eliminated by means of the present invention, which automatically ensures the correct sequence of the very sampling procedure.

The characteristic features of the invention appear from the enclosed



claims.

DESCRIPTION OF THE DRAWINGS

One embodiment of the invention will be described further in the following with reference to the enclosed drawings, wherein

5 Figure 1 in schematic perspective view illustrates how a device according to the invention is used together with an ultrasonic equipment for carrying out tissue sampling in accordance with the invention,

Figure 2 in top plan view illustrates a device according to the invention, viewed from above, with the cover which can be opened shown in the open position and with the needle unit shown in its final condition, when the
10 sampling has been carried out,

Figure 3 is a sectional view of the device according to Figure 1, with the needle unit shown in the same condition as in Figure 1,

Figure 4 shows the device viewed from below with its bottom plate
15 removed,

Figure 5 in top plan view illustrates another embodiment according to the invention, wherein the device is viewed from above with the cover which can be opened shown in the open position and with the needle unit not yet having been put in place, and

20 Figure 6 in bottom plan view shows the embodiment of Figure 5, the bottom plate of the device being removed in order to make internal elements visible.

DESCRIPTION OF PREFERRED EMBODIMENTS

Two embodiments will be described further in the following with
25 reference to the Figures of the drawings, in which the device according to the invention generally is designated by 1. Figure 1 schematically illustrates how one single doctor can perform a puncture according to the invention, the doctor with his one hand controlling the ultrasonic equipment 29, which is connected to a monitoring screen, and with his other hand controlling the device 1
30 according to the invention. Figure 1 further illustrates how a guiding device 30 is mounted at the ultrasonic equipment, which device 30 has an extension part 31 secured thereto and provided with a guide means 32 in the form of recesses or grooves in which the needle unit of the device is guided. In the drawing there is shown how a needle unit comprises an outer tubular needle 2 and an inner
35 needle 3 located therein. The outer hollow needle 2 is retained in a holder 4, the front part of which has a flange 5, which upon manual handling is used as a finger grip, but which in accordance with the invention is used as a fixation part for the attachment part 4 of the outer needle 2 in the device 1 according to the



invention. The inner needle 3 has its rearmost portion attached to a pressure plate 6 by means of the inner needle is manipulated.

The very device 1 according to the invention comprises a casing or box 7, a cover 8 which can be opened and closed, and a lower bottom piece 33 which is normally screwed up on the casing or box 7 and which is to be loosened only in connection with possible service.

Inside the box 7 there are two driving means, a rearward one driving the inner needle 3 and a forward one driving the outer needle 2. The rearward driving means consists of a spring 10 which in the shown embodiment is a pressure spring which can be biased from its inactive position, shown in the Figure, to an activated, compressed position in which the spring is retained behind a trigger lug 11. The trigger lug 11 can be operated from the exterior of the device by means of a trigger knob 12 which preferably is spring biased against its locking position and is connected to the trigger lug 11 (the trigger lug 11 and the knob 12 can preferably be made in one single piece and be interconnected by means of an intermediate piece which is journaled around a fulcrum so that depression of the knob 12 results in lifting of the trigger lug 11 from the position illustrated in the Figure). Thus, depression of the control knob 12 will actuate the trigger lug 11 so that the spring 10 is released from its compressed initial position and drives the reward pressure plate 6 for the inner needle 3 forwards to the desired extent.

It is suitable to design the triggering mechanism such that the very trigger-knob has a so-called pressure point. This means that no triggering takes place during the initial depression of the knob, but when the knob has been depressed to a suitable degree the resistance is increased, and when the button is depressed further then the very triggering takes place. The reason why a pressure point is desirable is that the user then will know with greater certainty when the very triggering will take place, at the same time avoiding unintentional triggering (e.g. by accident).

The outer needle 2 is driven by means of a forward driving means in the form of a spring 13, one end of which is firmly attached to a holding-up means 14 which is fixed in the box 7, the other end of the spring 13 contacting a cross-wall 15 of a displaceable slide 16, the front part of which has a lug 17 provided with two projections 18 and 19 respectively, between which the flange 5 of the part 4 is retained. The forward drive spring 13 can be compressed to a biased position by means of a tool, and the displaceable slide 16 has then been moved to the left in Figure 3 so far that a locking lip 20 of a locking and

triggering mechanism 21 engages and locks the movable slide. In this position the locking lip 20 has been brought into a hole 22 provided in a cross-piece 23 of the movable slide and the locking lug in this position holds the movable slide in this position, in which the spring 13 is compressed. The locking and triggering mechanism 21 has a trigger cam 24 at its lower part, which cam 24 extends through an intermediate partition 25 of the box 7 to be in the path of movement of the front end plate 26 of the rearward driving spring 10.

When the device according to the invention is to be used, it is prepared in the following way. The cover 8 is opened and the springs are tightened. Although it is possible to tighten the springs manually, it is at present considered suitable to use a special tool consisting of a goose-necked handle, by means of which the springs 10 and 13 respectively are conveniently tightened. The spring 13 then moves the displaceable slide 16 to the left in the Figures, and the locking lip 20 will then snap-in through the hole 22 in the cross-piece 23 and lock the movable slide in the position in which the spring is tightened. The locking and triggering mechanism 21 is biased to this locking position by means of a spring 27. The rearward drive spring 10 is tightened upon compression to the left in the Figures, and it will snap over the locking lug 11 of the triggering mechanism 12. Also this one is kept biased to the locking position by means of a biasing spring 28. The needle unit is inserted in the manner illustrated in Figure 1, the holder part of the outer needle 2 being put into the movable slide in a manner such that the flange 5 is in engagement with the projections 18 and 19 respectively of the lug 17. The rearward pressure plate 6 of the inner needle 3 is disposed adjacent the front end of the rearward drive spring 10 and it can suitably be kept in place by means of small lugs or ears, not shown, which are provided on the plate 26 and form a retaining means. The device is now prepared and ready for use.

Figures 5 and 6 show a second embodiment of the invention. The very basic construction is fully similar to that according to Figure 1, but the trigger knob 12 has been moved somewhat closer to the midpart of the device. Further, the drive springs for the two operational steps have been replaced, for the first step when the inner needle is to be brought forward by two draw springs 10A, 10B, while the spring which is to propel the outer needle 2 has been replaced by a pressure spring 13A. For the rest the second embodiment functions exactly in the same way as the first embodiment, and the other elements, which have not been mentioned here, completely correspond to the corresponding elements of the first embodiment.



When the device according to the invention is to be used in connection with tissue sampling by puncture the doctor uses his one hand for localizing, by means of an ultrasonic equipment, the place where a tissue sample is to be taken, while gripping with his other hand the device according to the invention, see Figure 1. He inserts the needle unit through the skin into the body and can monitor the penetration of the needle unit towards the intended place by means of the ultrasonic equipment. When the point of the needle unit is at the intended place, the doctor pushes the control knob 12, thereby causing the trigger lug 11 to leave its engagement with the front part of the spring 10. The spring 10 is then triggered and pushes the inner needle 3 to the right, and since the outer needle is not moved during this phase, the point of the inner needle will project a desired distance from the outer needle 2 and into the tissue from which a sample is to be taken. When the spring 10 approaches the end of its movement stroke it contacts the trigger lip 24, pressing the same upwards and turning s the locking and triggering mechanism 21 counter-clockwise in Figure 3. Thereby the locking lip 20 is lifted and leaves its engagement with the wall around the hole 22, thereby releasing the movable slide and pushing it forward under the action of the spring 13. Thereby the outer needle 2 is propelled and pushed over the inner needle 3 so that a tissue sample will be cut and retained in the space between the outer needle and the inner needle at the portion 34 of reduced diameter of the latter. The sampling has now been terminated and the doctor can withdraw the needle unit from the patient, leaving the tissue sample to a laboratory for testing.

The invention has been described above with reference to two suitable embodiments. However, a person skilled in the art realizes that the invention can be varied and modified within the scope of the basic idea of the invention. Thus, for example dual springs can be used in place of the two herein discussed forward and rearward springs 13 and 10 respectively, draw springs can be used instead of pressure springs, and some other type of triggering mechanism can be used. Thus, a common triggering mechanism for the two driving means 10 and 13 respectively can be provided, so that the trigger knob 12 at first can be depressed to a limited extent to the so-called pressure point, continued depression thereafter triggering the driving means 10 so that the same propels the inner needle 3 to the desired extent, whereupon further depression of the knob 12 results in triggering of the second driving means 13, so that the same causes the outer needle 2 to be propelled the intended extent. Further it is possible to use a separate trigger knob (similar to the knob 12) for the driving



means 10 for the inner needle 3, as well as a second separate trigger knob, which thus should be actuatable from the outside of the unit, for triggering the propelling motion of the second driving means 13. This latter case can make simplifications as to design possible, but at the same time there may arise a risk of faulty control since it is important, for achieving correct sampling, that the inner needle is triggered first to move a predetermined extent, whereafter the outer needle is to be propelled over the inner needle 3, so that a tissue sample can be caught in the space between the front part of the needles.

The entire device preferably ought to be made with an outer surface having good friction, for example being rifled or knurled, covered with friction-increasing projections or simply be provided with a stretched-on or glued-on friction material such as rough rubber material, for eliminating the risk that the user unintentionally slips with his hand during use. The device should be clean and easy to sterilize, and the user ought to use rubber gloves during use.

Finally, the invention in its most general scope also comprises other driving means than springs. For example, rechargeable compressed-air assemblies can be used, wherein a compressed-air cylinder is used for each of the two driving steps, alternatively the same compressed-air cylinder can be used for both of the driving steps.

INDUSTRIAL UTILITY

It is realized that the invention has industrial utility in that the need for tissue sampling equipment is increasing considerably by the possibility of making use of ultrasonic equipment for correct localization of the sampling place and of the correct place to locate the needle unit on sampling, and in that the invention provides a device which both makes one-man control service possible and guarantees a properly conducted procedure. This more and more increasing need demands series production of an equipment which should be simple and inexpensive to produce and easy and comfortable to handle. The invention offers such a device and may therefore find large industrial use by manufacture in large series. It is thus fully clear that the invention has industrial utility.



CLAIMS

1. A device for tissue sampling by means of so-called puncture, i.e. piercing of the skin from the outside with a needle unit which is inserted to the sampling place where a tissue sampling is taken, which sampling can take place under surveillance of ultrasonic equipment, the needle unit consisting of an independently actuatable outer hollow needle (2) and an independently actuatable inner needle (3) having a reduced portion (34) close to its point for accommodating the tissue sample after the tissue sampling has been performed, characterized in that the device (1) consists of a unit, in which the needle unit can be placed, a driving means (10) for propelling the inner needle (3), a driving means (13) for propelling the outer needle (2), and triggering means (11, 12; 20-24) for said driving means.

2. A device according to claim 1, characterized in that the device comprises a cover or a box (7), in which the needle unit (2-6) can be placed, a cover (8) which can be opened and closed, and a bottom piece (33).

3. A device according to claim 1, characterized in that said driving means (10, 13) consist of springs, and in that at least one (12) of said triggering means are actuatable from the outside of the device.

4. A device according to claim 3, characterized in that said triggering means comprise a first triggering lug (11) which is connected to the triggering means (12) which is actuatable from the outside, and is arranged to retain the driving means (10) propelling the inner needle (3) in its activated condition, prepared for propelling the needle.

5. A device according to claim 4, characterized in that the triggering means for the driving means (13) propelling the hollow outer needle (2) comprises a locking lip (20) of a locking and triggering mechanism (21), which locks said driving means (13) in its propulsion-activated condition and which has a portion (24) which can be actuated when the inner needle (3) has been propelled to its outermost position, so that propulsion of the outer hollow needle (2) occurs.

6. A device according to claim 5,



characterized in that said locking and triggering mechanism (21) engages with and locks a movable slide (16) which cooperates with the driving means (13) for the outer needle (2) and causes the propulsion thereof.

7. A device according to claim 4 or 5,
5 characterized in that said triggering means (11, 12; 20-24) are spring biased (28, 27) towards their locked conditions.

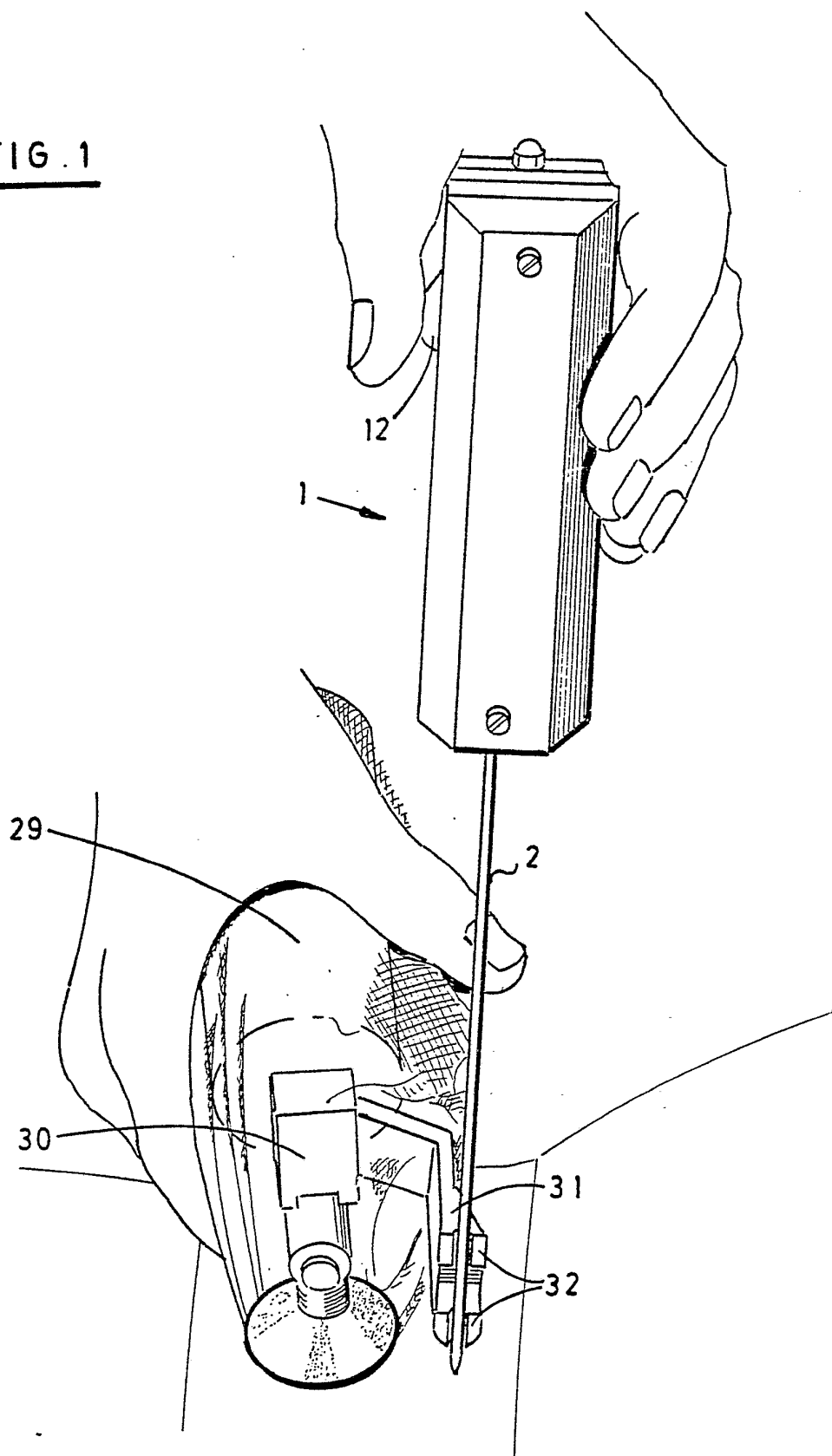
8. A device according to claim 5 or 6,
characterized in that the locking and triggering mechanism (21) for starting the propulsion of the outer needle (2) comprises a triggering cam (24) provided in
10 the path of movement of the driving means (10) for the inner needle (3), so that the triggering means (20-24) automatically will trigger the outer movement of the outer needle (2) when the inner needle (3) has finished its movement or is close to the end of its movement.

9. A device according to claim 4 or 5,
15 characterized in that the triggering means (12), which can be actuated from the outside, is provided with a distinct pressure point, and in that the locking and triggering mechanism (21) for the propelling motion of the outer needle (2) is triggered by a further depression of the triggering means (12), which can be actuated from the outside, after the same has triggered the movement of the
20 inner needle (3).

10. A device according to any one of the preceding claims,
characterized by a guiding means (30-32) intended for correct positioning and connected to the ultrasonic equipment (29) and comprising guide grooves (32), in which the needle unit (2, 3) is guided during the very tissue sampling.

1/5

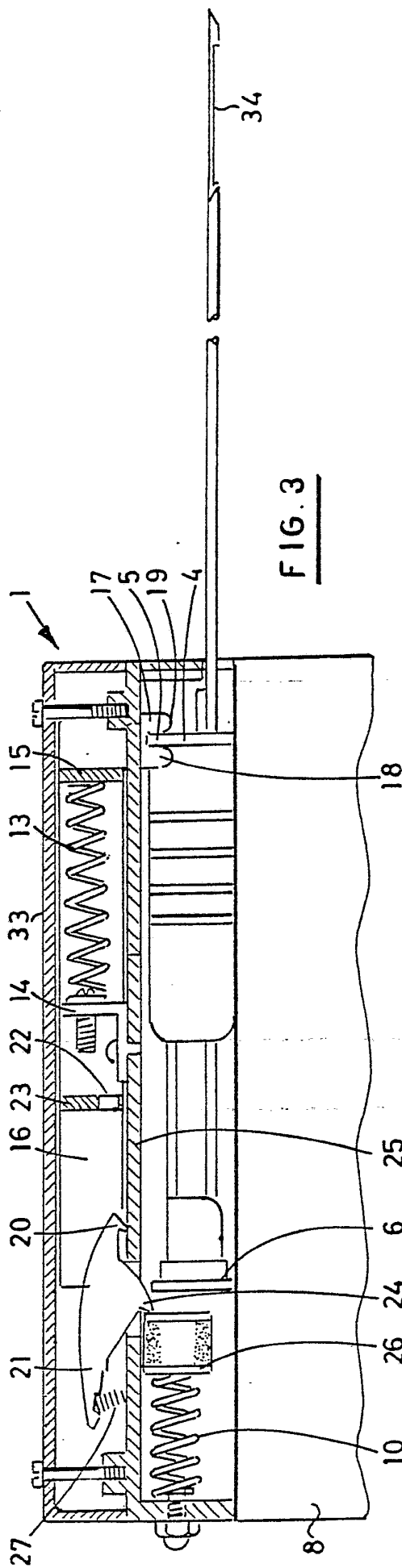
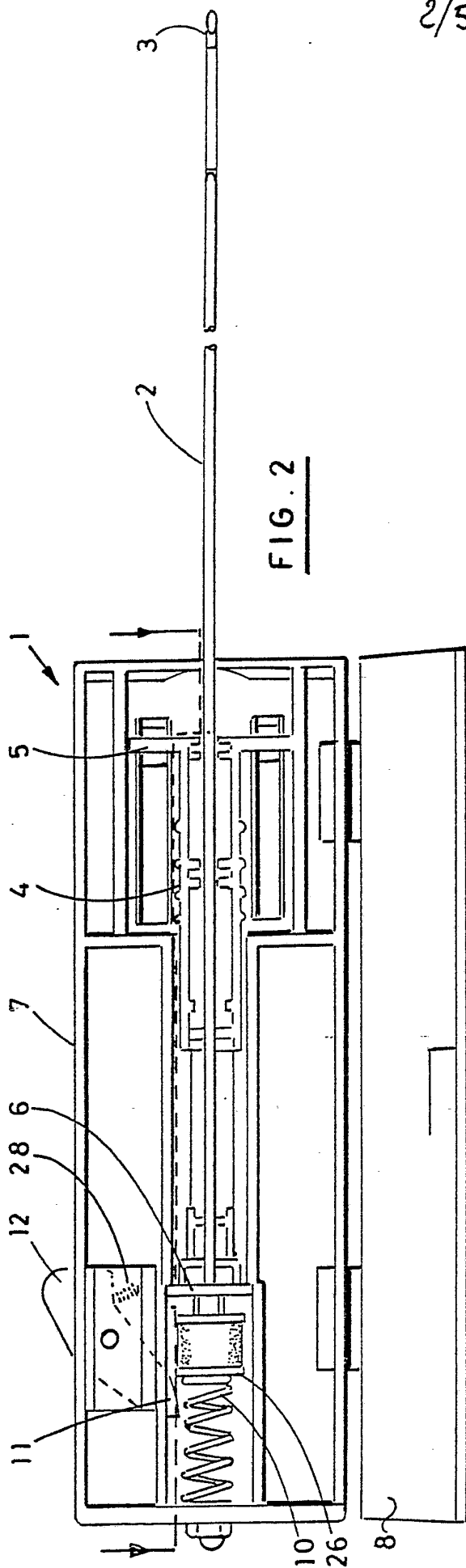
FIG. 1



SUBSTITUTE SHEET



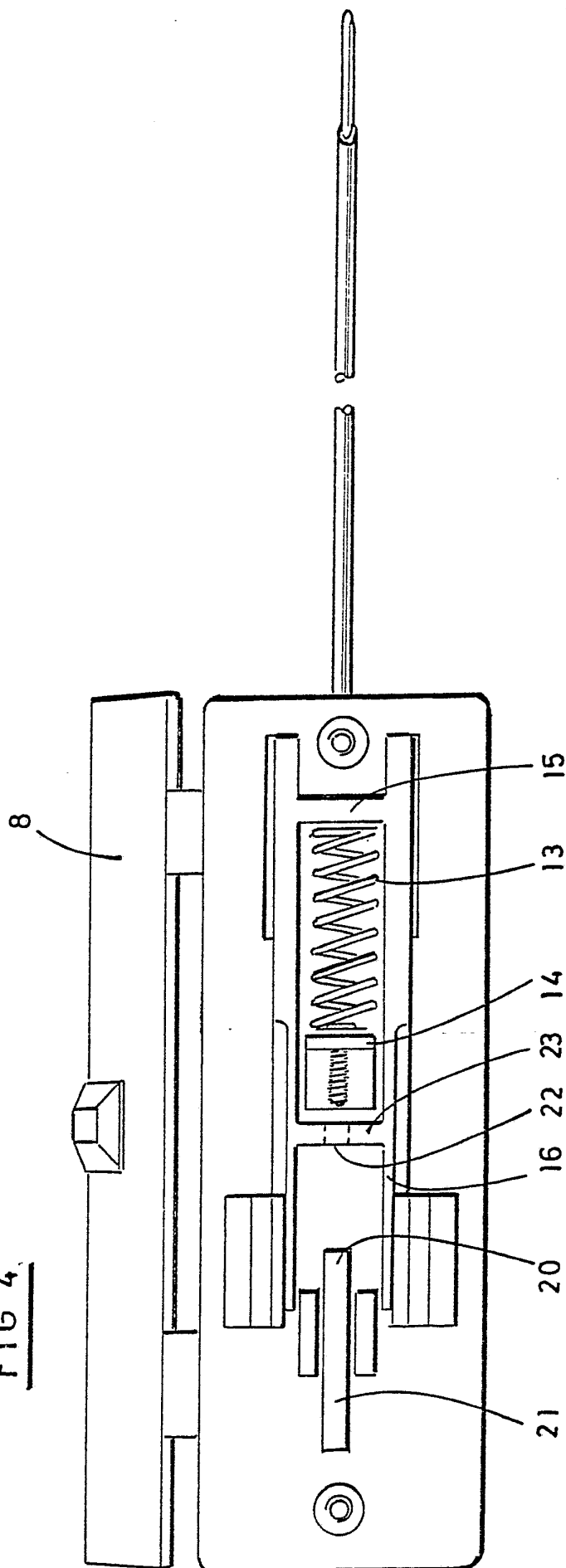
2/5



SUBSTITUTE SHEET

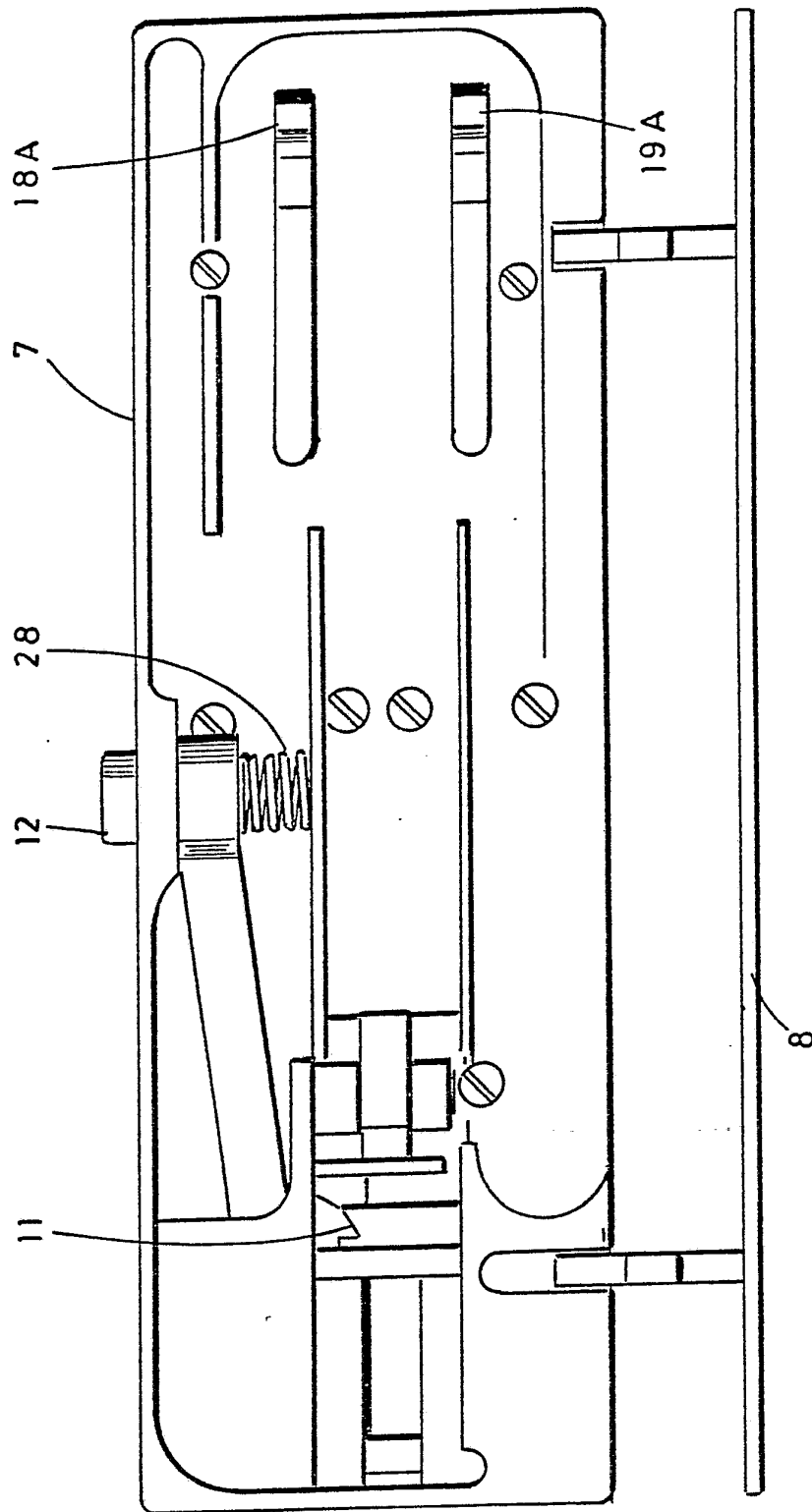


FIG 4



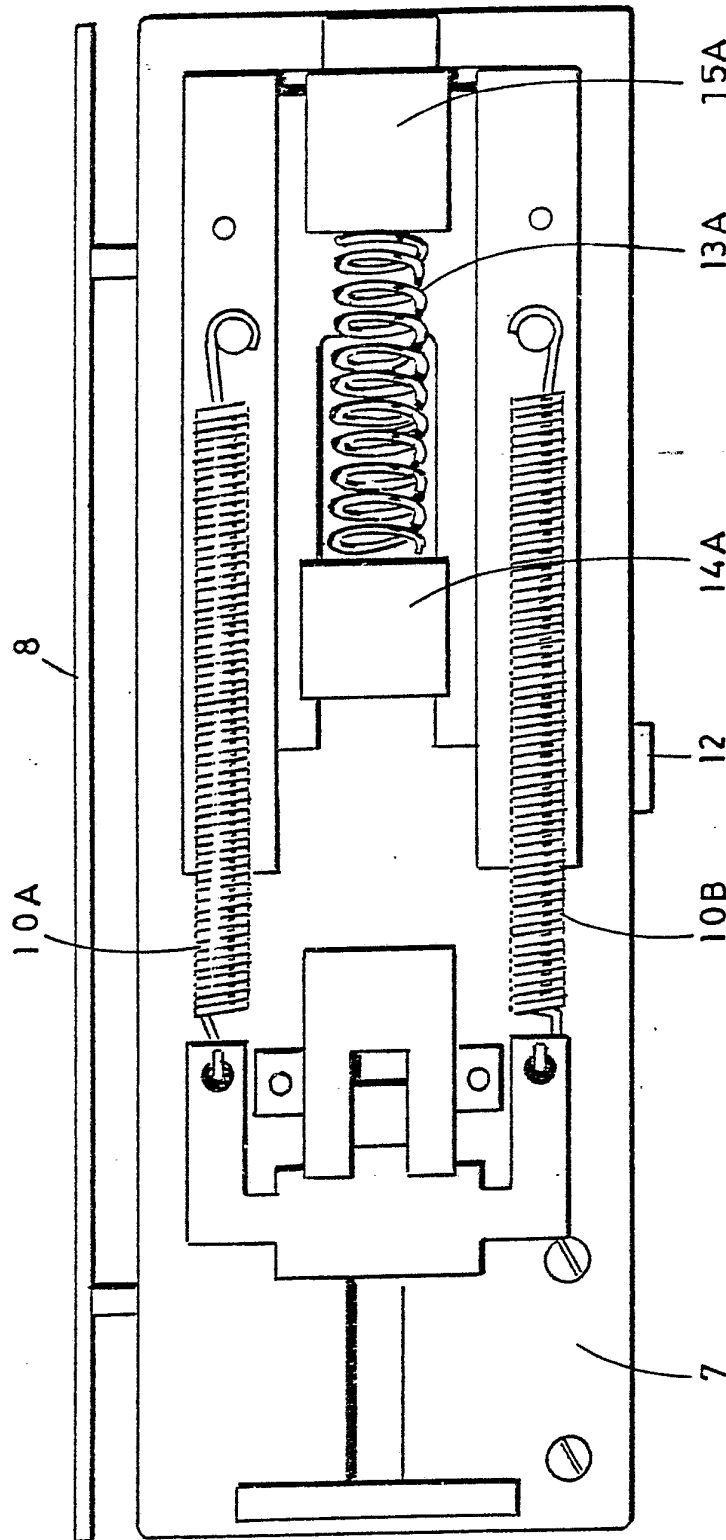
4/5

FIG. 5



5/5

FIG 6



INTERNATIONAL SEARCH REPORT

International Application No PCT/SE83/00112

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) ¹

According to International Patent Classification (IPC) or to both National Classification and IPC ³

A 61 B 10/00

II. FIELDS SEARCHED

Minimum Documentation Searched ⁴

Classification System

Classification Symbols

IPC 3
US C1

A 61 B 10/00
128: 2B, 2R, 749, 751-755

Documentation Searched other than Minimum Documentation
to the Extent that such Documents are Included in the Fields Searched ⁵

SE, NO, DK, FI classes as above

III. DOCUMENTS CONSIDERED TO BE RELEVANT ¹⁴

Category ⁶	Citation of Document, ¹⁶ with Indication, where appropriate, of the relevant passages ¹⁷	Relevant to Claim No. ¹⁸
XY	CH, A , 483 829 (DR H REINISCH) 27 February 1970	1-8
Y	DE, A1, 2 936 259 (SIEMENS AG) 19 March 1981	10

* Special categories of cited documents: ¹⁵

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search ¹

1983-06-07

Date of Mailing of this International Search Report ²

1983-06-29

International Searching Authority ¹

Swedish Patent Office

Signature of Authorized Officer ²⁰

Gunnar Hilderot