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<p>(21) International Application Number: PCT/DK92/00162 (22) International Filing Date: 14 May 1992 (14.05.92) (30) Priority data: 919/91 15 May 1991 (15.05.91) DK (71)(72) Applicant and Inventor: WEIBEL, Stig, Eric [DK/DK]; Boserupvej 119, DK-3050 Humlebæk (DK). (74) Agent: LEHMANN & REE A/S; Grundtvigsvej 37, Dk- 1864 Frederiksberg C (DK). (81) Designated States: AT (European patent), AU, BB, BE (Eu- ropean patent), BF (OAPI patent), BG, BJ (OAPI pa- tent), BR, CA, CF (OAPI patent), CG (OAPI patent), CH (European patent), CI (OAPI patent), CM (OAPI patent), CS, DE (European patent), DK (European pa- tent), ES (European patent), FI, FR (European patent), GA (OAPI patent), GB (European patent), GN (OAPI patent), GR (European patent), HU, IT (European pa- tent), JP, KP, KR, LK, LU (European patent), MC (Eu- ropean patent), MG, ML (OAPI patent), MN, MR (OA- PI patent), MW, NL (European patent), NO, PL, RO, RU, SD, SE (European patent), SN (OAPI patent), TD (OAPI patent), TG (OAPI patent), US.</p>		<p>Published <i>With international search report.</i></p>
<p>(54) Title: BLOOD TAKING DEVICE</p>		
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<p>(57) Abstract</p>		
<p>A blood taking device has a cylindrical needle holder (1) carrying or adapted to carry a double needle (6, 7) and being slidably mounted in a safety shield (4). A resilient finger grip (13) is fixed to the unbroken wall of the holder (1) and extends out of a longitudinal slot (15) of the shield (4). Outside the shield the finger grip has parts (74, 75) which are resiliently urged from outside towards the shield (4) and are constructed with a locking nose (76) engageable from outside in a first widened slot (19) and a second widened slot (20) of the shield to define an advanced blood taking position and a retracted holding position of the finger grip (13), respectively. The longitudinal slot (15) extends rearwardly beyond the second widened slot to permit further retraction of the finger grip (13) to a definitive locking position. Preferably, the shield (4) has a third widened slot (77), through which a rearwardly directed tongue (75) of the finger grip (13) can be pressed inwards to a shielding position behind the rear needle (7) to establish the definitive locking position. In a device having a fixedly mounted double needle (6, 7) the front needle (6) can advantageously be encapsulated in a needle sheath (40) which is removably connected with the front end of the holder (1) in contamination-proof manner.</p>		

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Blood Taking Device.

The invention relates to a blood taking device of the kind set forth in the introductory clause of claim 1.

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Such devices are usually made from plastic materials (apart from the needles). As an example of a material, which is widely used in the medico-plastic industry owing to its favourable hygienic and environmental properties, polypropylene may be mentioned.

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A blood taking device of the kind referred to is known from PCT/DK88/00186, published on 18th May 1989 under publication number WO 89/04141.

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In all the embodiments disclosed in PCT/DK88/00186 the finger grip element comprises a resilient tongue formed in the wall of the holder and carrying both the finger grip and the locking nose. In the blood taking position and the holding position the locking nose engages the first and the second widened slot, respectively, from inside under the influence of the resiliency of the tongue, and can be pressed inwardly out of this engagement by depressing the finger grip, which can thereafter be freely retracted or advanced along the length of the longitudinal slot of the shield.

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The device is delivered by the manufacturer with the finger grip in the holding position and with the resilient tongue flush with the wall of the holder. When the device is to be taken into use, the operator takes the device in his hand, depresses the finger grip and advances it to the blood taking position. During this movement the tongue assumes an inwardly bent position, and when the locking nose arrives at the location of the first widened slot, and the operator lifts his finger from the finger grip, there is a risk that the tongue will not spring back fully to its original position flush with the wall of the holder. In that case the front end of the tongue will assume a position inside the circumference of the wall of the holder. This may give rise to serious difficulties when a sampling tube is later to be introduced into and pressed home in the holder.

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It is the object of the invention to provide a device of the kind referred to, in which the drawback described above is avoided without requiring the use of plastic materials having a particularly high degree of elasticity, or of supplemental spring means embedded
5 in the resilient finger grip element.

This object is achieved, according to the invention, by constructing the device as set forth in the characterizing clause of claim 1.

10 In a device so constructed a blood sampling tube can always be slid smoothly into the holder and further forwards to an end position in which its front end closure is pierced by the rear needle, and moreover, since the resilient elements activating the locking nose are located outside the shield, there is a considerable freedom to
15 design these elements in such a manner as always to preserve a satisfactory resiliency of these elements for proper function, even if they are made from a plastic material having a relatively poor degree of elasticity.

20 Further objects and features of the invention will be apparent from the following description of embodiments with reference to the drawings, in which

Fig. 1 shows a device according to a first embodiment of the invention, as viewed in vertical section, with the finger grip in the
25 blood taking position,

Fig. 2 a similar view of the same device with a screwed-in double needle and with the finger grip set free by finger pressure,

30 Fig. 3 a similar view of the same device with a blood sampling tube in position for blood taking,

Fig. 4 a similar view of the same device with a blood sampling tube
35 of a different type in position for blood taking,

Fig. 5 a similar view of the same device with the finger grip in an intermediate position between the blood taking position and the holding position,

Fig. 6 a top view corresponding to Fig. 5,

Fig. 7 a vertical section through the same device with the finger grip in the holding position,

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Fig. 8 a vertical section through the same device, but with the finger grip in the definitive locking position,

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Fig. 9 a vertical section through the holder alone, with screwed-in double needle,

Fig. 10 the holder alone, as seen from the rear end,

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Fig. 11 a vertical section through a device according to a second embodiment of the invention, with the holder in an intermediate position,

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Fig. 12 a longitudinal section through a standard sterilized double needle that may be used for the devices of Figs. 1-10 and 11,

Fig. 13 a vertical section through a device according to a third embodiment of the invention, with the finger grip in the holding position,

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Fig. 14 the device of Fig. 13 with the finger grip in the definitive locking position,

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Fig. 15 a vertical section through a device according to a fourth embodiment of the invention, with the finger grip in the definitive locking position, and

Fig. 16 a section along the line XVI-XVI in Fig. 15.

The blood taking device illustrated in Figs. 1-10 has a substantially cylindrical needle holder 1 with an inner space 2 which is open at its rear end for receiving an evacuated blood sampling tube, and is closed by a bottom 3 at its front end. In front of the bottom the holder 1 has a solid tapering portion 5. In the bottom 3 there is formed an undercut recess 3a that may be used for the fixation of a

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reduction holder for receiving sampling tubes having a smaller diameter than that for which the device is primarily designed, or the fixation of other auxiliary equipment.

- 5 The holder 1 is slidably mounted in a cylindrical safety shield 4 which is open at its rear end, and at its front end has a tapering wall portion 9 within which the tapering portion 5 of the holder fits in the frontmost position of the holder.
- 10 In contradistinction to the devices disclosed in PCT/DK88/00186 the cylindrical wall of the holder is unbroken and directly carries a resilient finger grip 13 comprising a stem 73 which extends out through a longitudinal slot 15 of the shield 4 and outside the shield carries a forwardly directed tongue 74 and a rearwardly
15 directed tongue 75, the outer faces of which are shaped for engagement by a finger for retracting and advancing the finger grip 13 along the slot 15. Both tongues have a width exceeding that of the slot 15 and are resiliently urged towards the shield from 4 outside.
- 20 The forwardly directed tongue 74 has on its underside a locking nose 76, which is likewise wider than the slot 15, but is engageable in a first and a second widened portion 19 and 20, respectively, of the slot, in the following referred to as widened slots, thereby defining an advanced blood taking position and a retracted holding
25 position, respectively, of the finger grip 13 and thereby of the holder 1. When the finger grip is locked by the nose 76 in either of these positions, it can be released by exerting a finger pressure on the rearwardly directed tongue 75, whereby the finger grip 13 is tilted so as to disengage the locking nose 76 from the widened slot
30 19 or 20, as illustrated in Fig. 2, so that the finger grip 13 is set free for displacement along the longitudinal slot 15. In the rearward direction this slot extends beyond the widened portion 20 for a purpose to be described later.
- 35 The solid end portion 5 of the holder 1 has a hole 71 with an internal thread 72 for screwing in a sterilized standard double needle 6,7 with a pierceable and self-closing bag-shaped membrane 21 in well-known manner.

The device of Figs. 1-10 can advantageously be used in the following manner.

5 The device is delivered with the finger grip in the holding position (Fig. 7), but without a screwed-in double needle.

When the device is to be made ready for use, the finger grip 13 is set free by pressing the rearwardly directed tongue 75 and is advanced to the blood taking position (Fig. 1), and a sterilized
10 double needle 6,7 is screwed in in well-known manner.

If the device is to be used for blood taking immediately after the device has thus been made ready, the needle which has just been screwed in, is immediately stuck into a vein of the patient, and an
15 evacuated blood sampling tube 22, Fig. 3, or 51, Fig. 4, is introduced through the open end of the shield 4 and pushed forwards into the holder and pressed home to an end position in which its end closure is pierced by the rear needle 7, while the bag-shaped membrane 21, after having been pierced first, is axially compressed
20 into accordion-like folds around the rear needle 7, as illustrated in Figs. 3 and 4. Now blood is sucked from the vein into the sampling tube 22, 51 under the influence of the vacuum therein.

If the device is not to be used for blood taking immediately after
25 the standard double needle has been screwed in, the finger grip 13 is tilted free (Fig. 2) and retracted to the holding position (Fig. 7) and remains there, until blood taking is to be performed. It is then again advanced to the blood taking position (Figs. 3 and 4), and blood taking is commenced in the same manner as described above.
30 In the meantime the front needle 6 has been held in a shielded position within the safety shield 4.

The device is constructed for receiving two different well-known types of blood sampling tubes, viz. a tube 22, Fig. 3, with an end
35 closure in the form of a pierceable and self-closing stopper 23 having a recess 24 in its front end, and a tube 51, Fig. 4, having an end closure in the form of a metal foil 53 glued to a collar 52 at the front end of the tube and provided at its middle with a pierceable pad 54 of self-locking membrane material, such as natural

rubber. The latter type of sampling tube could not be pressed home against the bottom 3 of the inner space 2 of the holder 1, because the metal foil 53 would then be destroyed by the compressed bag-shaped membrane 21. The wall of the holder is therefore constructed with an annular shoulder 55, against which the collar 52 can be pressed. To reduce the risk of accidental premature expulsion of the blood sampling tube during the taking of a blood sample under the influence of the rearwardly directed pressure by the compressed bag-shaped membrane 21, the wall of the holder is constructed with a slightly protruding, flatly rounded internal bead 56 behind the position occupied by the collar 52 in the blood taking position.

When the amount of blood determined by the vacuum in the sampling tube has been sucked into the tube, this is pulled out of the holder and the safety shield. The stopper 23 or pad 54 is automatically reclosed, and the tube 22 or 51 is ready for analyzing or testing the blood sample by well-known methods. The bag-shaped membrane 21 expands to its original shape and is automatically re-closed. If a further sample is to be taken from the same vein, a new sampling tube is pushed into and pressed home in the holder 1 and is again extracted when the new sample has been taken. This procedure can be repeated any number of times, until the desired number of samples has been taken from the same vein.

If it is now intended to re-use the device with a fresh sterilized standard double needle - which may in some circumstances be compatible with safety regulations and the responsibilities of the user - the finger grip is retracted to the holding position and remains there until the device has been brought into position above a standard tool for unscrewing the needle above a waste container.

The device can thereafter be made ready for use in the same manner as previously described.

When the device is to be finally disposed of - which may be after a single venipuncture sequence or after a limited number of venipuncture sequences - the finger grip 13 is retracted along the slot beyond the holding position to a definitive locking position. PCT/DK88/00186 discloses how a definitive locking in a further

retracted position can be obtained by means of recesses in the wall of the holder and corresponding locking hooks on the inner wall of the shield. Definitive locking means of this or similar kind could also be used in combination with the novel finger grip structure of the present invention. However, the invention also provides for definitive locking means, by which a considerably increased safety is obtained in the disposal of the device, such as will be apparent from the following description.

10 Besides the first widened slot 19 and the second widened slot 20, the shield 4 has a third widened slot 77 at the end of the longitudinal slot 15 extending beyond the second widened slot 20. The rearwardly directed tongue 75 has at least at its rear end a width such that it cannot engage the second widened slot 20. When the
15 finger grip is retracted from the blood taking position, the rearwardly extending tongue 75 will therefore slide past the second widened slot 20, and the user can continue retraction of the finger grip 13 to the holding position, in which the locking nose 76 engages the second widened slot 20 and can only be released from
20 this engagement by exerting a pressure on the rearwardly directed tongue 75 for tilting the finger grip in the same manner as illustrated in Fig. 2.

The third widened slot 77 is wider than the first and second widened
25 slots 19,20, and its front edge is so located that in the holding position the end of the rearwardly directed tongue 75 can be received in the slot with the tongue 75 in a substantially relaxed state, as illustrated in Fig. 7.

30 When the device is to be finally disposed of, the finger grip 13 is retracted beyond the holding position, and by finger pressure on the forwardly directed tongue 74 the finger grip 13 is tilted inwards, so that the rearwardly directed tongue 75 is pressed inwards through the third widened slot to a shielding position behind the rear
35 needle 7, as illustrated in Fig. 8, while at the same time an abutment 78 on the stem 73 is brought into definitive locking engagement with the front edge of the third enlarged slot 77 from below. The device is now secured against re-use, and both the front needle 6 and the rear needle 7 are fully encapsulated, so that the

device can be dropped into a waste container or bag without any risk of spreading infection.

5 The embodiment illustrated in Fig. 11 differs from that of Figs. 1-10 in that the front end of the shield is constructed with a cylindrical extension 81 having an inner diameter sufficiently great for permitting the front cap 87 of a standard sterilized double

10 To facilitate understanding, a standard sterilized double needle, such as delivered by the manufacturer, is illustrated in Fig. 12. It consists of a front needle 6 and a rear needle 7 forming a unit which is fixedly mounted in a hub 83 having a forwardly directed hexagonal head 84 and rearwardly of that an externally threaded

15 portion 85 and an extension 86 on which a bag-shaped membrane 21 is held in position by its elasticity so as to form an enclosure around the rear needle, as previously explained. The double needle 6,7 is encapsulated in a sterile manner between a front cap 87 with an internally hexagonal head 88 frictionally engaged with the hexagonal

20 head 84 of the hub 83, and a rear cap which is frictionally engaged with the rear end of the front cap and rests against an annular projection 90 of the front cap.

25 The device of Fig. 11 can be used in exactly the same manner as that of Figs. 1-10, but it can also be used under more primitive conditions where an unscrewing tool with associated waste container is not available.

30 When the device of Fig. 11 is to be made ready for use, the finger grip 13 is advanced to the blood taking position. The rear cap 89 is pulled off and put aside for easy retrieval, and the rear needle with the surrounding bag-shaped membrane 21 is introduced through the cylindrical extension 81 of the shield 4 and pushed further rearwards until the external thread 85 of the hub 83 meets the front

35 end of the internally threaded hole of the holder. The needle assembly is then screwed home by turning the front cap 87, which is still accessible in front of the shield. Thereafter the front cap 87 is pulled off the hexagonal head 84 and out of the shield 4 and is put aside for easy retrieval, so that the front needle is now

denuded in its advanced position and the device is thus ready for blood-taking. If the device is not to be used immediately, the finger grip 13 may in the meantime be retracted to the holding position where the front needle 6 is protected against touching.

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In the procedure so far described, there is no difference from the device of Figs. 1-10.

10 It is, however, possible after the completion of a blood taking sequence to remove the used needle manually without the use of an unscrewing tool. This takes place as follows:

15 The finger grip 13 is moved to the holding position, if it is not already in that position. The front cap 87, which was earlier put aside, is gripped and pushed in through the front end of the cylindrical extension 81 of the shield so as to loosely surround the front needle 6. The finger grip 13 is set free and is advanced to an intermediate position, corresponding to that illustrated in Fig. 11, where the front end of the holder 1 meets the rear end of the cap 20 87, and the front end of the latter still extends out of the front end of the shield extension 81. By simultaneously exerting a forward pressure on the finger grip 13 and a rearward pressure on the cap 87, the internally hexagonal head 88 of the front cap 87 is driven in on the hexagonal head 84 of the needle hub, as illustrated in 25 Fig. 11. By turning the front cap 87, the whole needle assembly including the rear needle 7 and the bag-shaped membrane 21 can now be unscrewed from the threaded hole at the front end of the holder and pulled out of the front end of the shield 4. Thereafter, the rear cap 89 which was earlier put aside, can be re-applied around 30 the rear needle 7 and the membrane. Now the double needle 6,7 is no longer sterile, but since it is entirely encapsulated between the front and rear caps, it can safely be dropped into a waste container or bag.

35 When the device is to be made ready for disposal in its entirety, this takes place in the same manner as described with reference to Figs. 1-10.

The embodiment illustrated in Figs. 13 and 14 differs from that of

Figs. 1-10 in that the double needle 6,7 is fixedly mounted in the solid front portion 5 of the holder 1. Apart from that, the structural arrangement and the operation of the holder, the finger grip and the shield are the same, and the parts are denoted by the same reference characters.

In the use of the device of Figs. 13 and 14, this should of course be disposed of, with the finger grip in the definitive locking position, after the completion of a single venipuncture sequence, that may comprise the taking of a number of blood samples from the same vein.

The device of Figs. 13 and 14 embodies a further important feature of the invention, which will now be described.

The front needle 6 of the device, as delivered, is enclosed in a needle sheath 40, which is connected with the holder 1 by the engagement of a rounded bead on an extension 42 of the holder 1 in a correspondingly rounded annular recess 43 in the wall of the needle sheath 40 close to its rear end. The head 41 and the recess 43 form a snap-lock, that can be broken by an energetic pull. In the production of the device the needle sheath 40, the needle 6,7, the bag-shaped membrane 21, and the holder 1 are sterilized, and the needle can thereby be maintained sterile during storage, transportation and handling right up to the moment when the needle is advanced to the blood-taking position and contact with the surrounding air is anyhow unavoidable. Since the shield 4 is not to be sterilized, sterilization costs are reduced, and it becomes redundant to pack each device in a sterile bag, whereby many practical advantages are obtained. Thus, a number of devices can be packed tightly together in a box whereby shipment costs are considerably reduced. The same applies to space requirements for internal storage and transportation. When taking the device into use, the user can take the device directly in his hand without first having to peel off a sterile bag, which is an irksome and time consuming step.

The needle sheath 40 is provided at its front end with a gripping portion 44 which in the holding position of the holder 1 (Fig. 13) extends out of the front end of the shield 4, while the front needle

6 itself is still located entirely inside the shield 4.

5 When the device is to be taken into use, the user takes it in one hand without pressing the finger grip 13, and with his other hand grips the gripping portion 44 and pulls the needle sheath 40 out through the front end of the shield 4. This can be done without risk of touching the front needle 6, because the holder 1 is withheld in the holding position by the engagement of the locking nose 76 in the second widened slot 20.

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In the region inside the front end of the shield 4 the needle sheath 40 has a bead or collar 45 with a sloping front side and a steep rear side. This acts like a barb which permits extraction of the needle sheath through the front end of the shield, but prohibits re-insertion of the needle sheath. Thus, when the needle sheath 40 is present in correct position, this is the user's guarantee that the needle is sterile. The colour of the gripping portion 44 extending out of the holder may be utilized for indicating the needle dimension in accordance with an internationally standardized colour code system.

20

The embodiment of Figs. 15 and 16 corresponds to that of Figs. 13 and 14, but illustrates the additional feature of arranging the rearwardly directed tongue 75 in such a manner that when pressed inwards through the third widened slot 77, it will strike the rear end of the rear needle 7 so as to distort the rear needle 7 away from its axially aligned position. To improve this function, the rearwardly directed tongue 75 may be constructed on its inner side with a rib-like projection 91, which will exert a direct perpendicular pressure on the needle 7. The projection 91 is narrower than the longitudinal slot 15 of the shield 4, so that it will not interfere with the relaxed condition of the rearwardly extending tongue 75 in the holding position of the finger grip 13, cf. Figs. 7 and 13.

30

35 By the distortion of the rear needle 7 the device becomes irreparably inoperative for blood sampling, so that any attempt at renewed advancing of the finger grip from the definitive locking position by abusive manipulation will be futile.

C L A I M S.

1. A blood taking device comprising a substantially cylindrical
needle holder (1) which is adapted to receive an evacuated blood
5 sampling tube and at its front end carries or is adapted to carry a
double needle (6,7) consisting of a front needle (6) and a rear
needle (7), the holder being slidably mounted in a safety shield (4)
and being guided for longitudinal movement therein by means of a
10 resilient finger grip element carried by the holder (1) and having a
finger grip (13) extending through a longitudinal slot (15) of the
shield, the finger grip element having a locking nose (76) engageable
under the influence of the resiliency of the finger grip element
in a first and a second widened slot (19,20) of the shield (4),
15 respectively defining an advanced blood taking position of the
finger grip and holder in which the front needle (6) extends out of
the front end of the shield (4), and a retracted holding position in
which the front needle (6) is completely enclosed within the shield
(4), the finger grip being releasable from each of said positions by
20 finger pressure, the finger grip being further retractable beyond
said holding position to a definitive locking position in which
locking means of the holder and the shield are irreversibly interen-
gaged, characterized in that the finger grip (13) is carried direct-
ly by the unbroken cylindrical wall of the holder (1) and is in
itself resilient and so constructed as to be inwardly urged towards
25 the outer surface of the shield (4), and that said nose (76) is
carried by the finger grip (13) in a position such as to be engage-
able in said first and second widened slots (19,20) from outside.

2. A blood taking device as in claim 1, **characterized in** that the
30 finger grip (13) comprises a stem (73) which is carried by the
cylindrical wall of the holder (1) and extends out through the
longitudinal slot (15) of the shield (4) and outside the shield
carries a forwardly directed tongue (74) and a rearwardly directed
tongue (75), the upper faces of which are shaped for engagement by
35 a finger for retracting and advancing the finger grip (13),

the locking nose (76) for engaging said first and second
widened slots (19,20) from outside being provided on the underside
of the forwardly directed tongue (74),

the finger grip (13) being so dimensioned that said nose (76)

on the forwardly directed tongue (74) is resiliently engaged in said first and second widened slots (19,20) in the blood taking position and the holding position, respectively, and is tiltable out of such engagement by finger pressure on the rearwardly directed tongue (75).
5

3. A blood taking device as in claim 2, **characterized in** that the shield (4) has a third widened slot (77) which is wider than the first and second widened slots (19,20) and is so located that in the holding position of the finger grip (13) the end of the rearwardly directed tongue (75) extends beyond the front edge of the third widened slot (77) so that the rearwardly directed tongue (75) rests on said front edge in a substantially relaxed state, the rearwardly directed tongue (75) being so shaped that it cannot penetrate into the second widened slot (20).
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4. A blood taking device as in claim 3, **characterized in** that the finger grip (13), when retracted from the holding position, is inwardly tiltable in such a manner as to press the rearwardly directed tongue (75) inwards through the third widened slot (77) to a shielding position behind the rear needle (7), while at the same time an abutment (78) on the stem (73) is brought into definitive locking engagement with the front edge of the third widened slot (77).
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5. A blood taking device as in claim 4, **characterized in** that the rearwardly directed tongue (75) is adapted, when pressed inwards through the third widened slot (77), to strike the rear end of the rear needle so as to distort the rear needle away from its axially aligned position.
30

6. A blood taking device as in any of the foregoing claims, in which the double needle is fixedly mounted at the front end of the holder, **characterized in** that the front needle (6) is encapsulated in a needle sheath (40) which is removably connected with the front end of the holder (1) in contamination-proof manner.
35

7. A blood taking device as in claim 6, **characterized in** that the needle sheath (40) is provided at its front end with a gripping

portion (44) which in the holding position of the holder (1) extends out of the front end of the shield (4).

5 8. A blood taking device as in claims 6 or 7, characterized in that the needle sheath (40) is connected with the holder (1) by means of co-operating snap-locking means (41,43) at the rear end of the needle sheath (40) and the front end of the holder (1).

10 9. A blood taking device as in any of claims 6-8, characterized in that the needle sheath (40) is constructed with a barb-like bead or collar (45) which permits extraction of the needle sheath through the front end of the shield (4), but prohibits re-insertion of the needle sheath (40).

15 10. A blood taking device as in any of the foregoing claims, characterized in that the inner wall of the holder (1) is constructed with an annular shoulder (55) at a distance rearwardly of the bottom (3) of the holder, and with an inwardly protruding, flatly rounded bead (56) at a distance rearwardly of said annular shoulder
20 (55).

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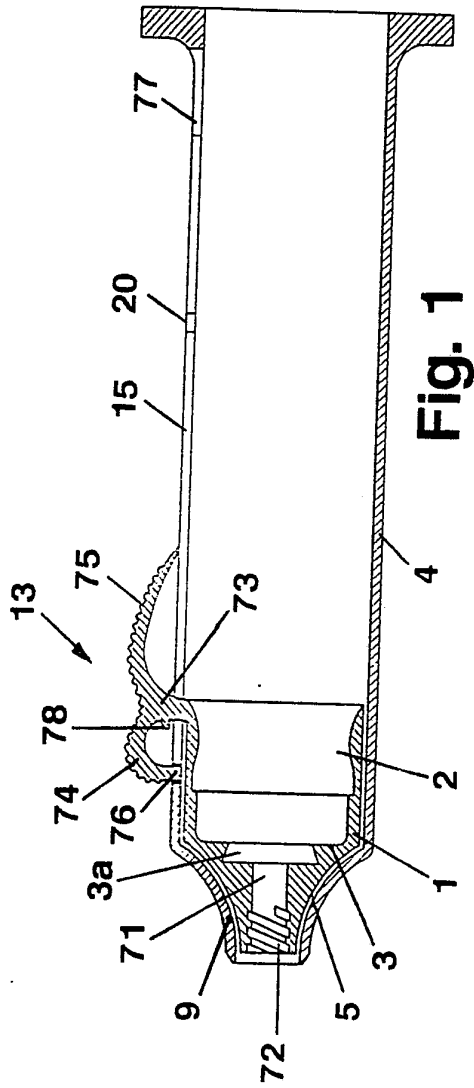


Fig. 1

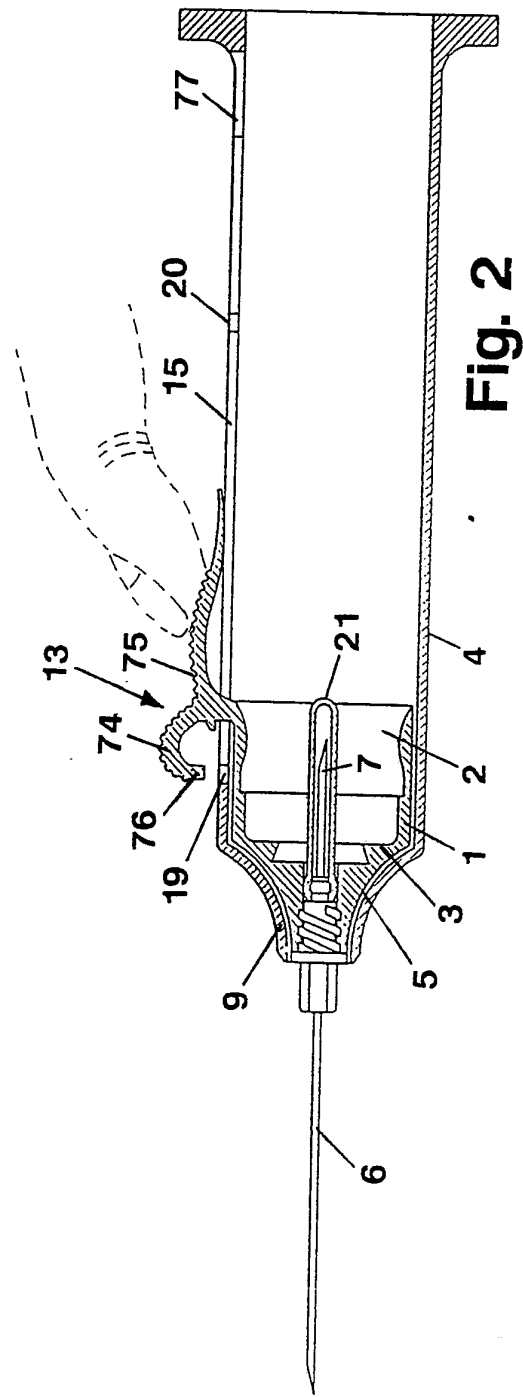


Fig. 2

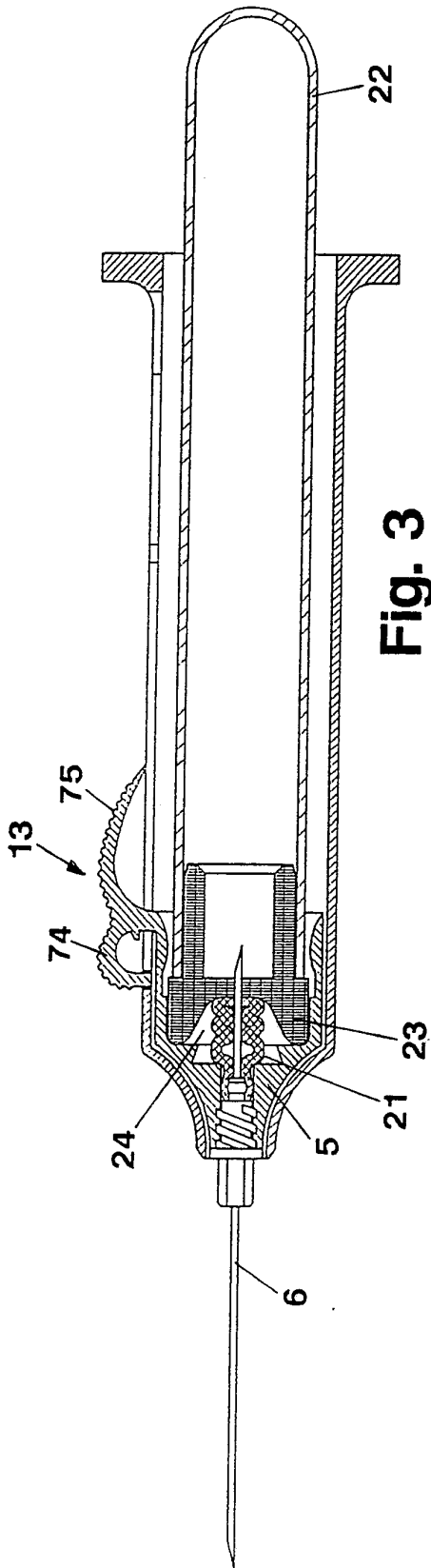


Fig. 3

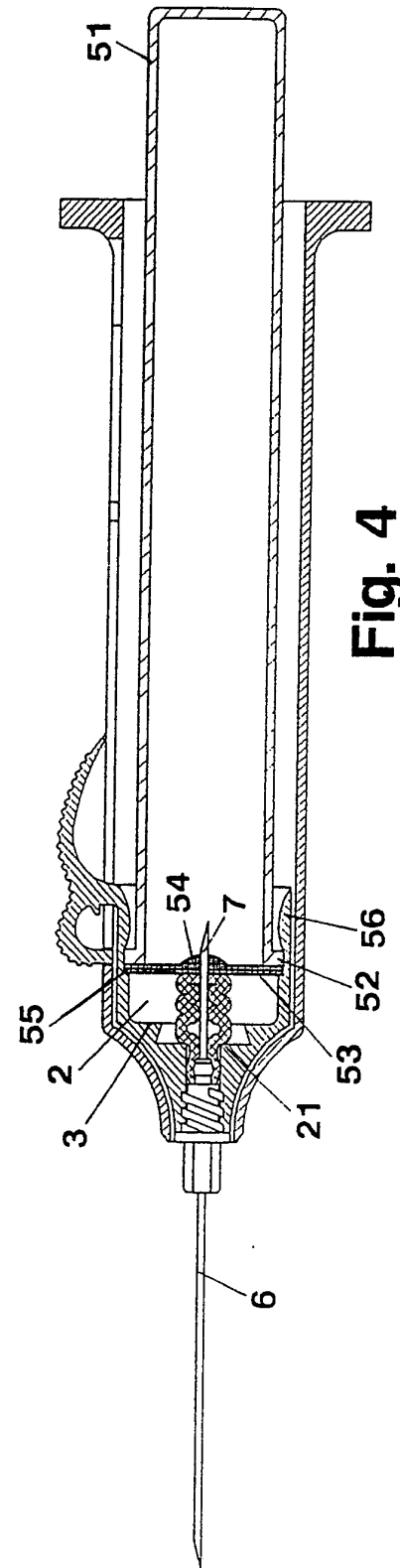


Fig. 4

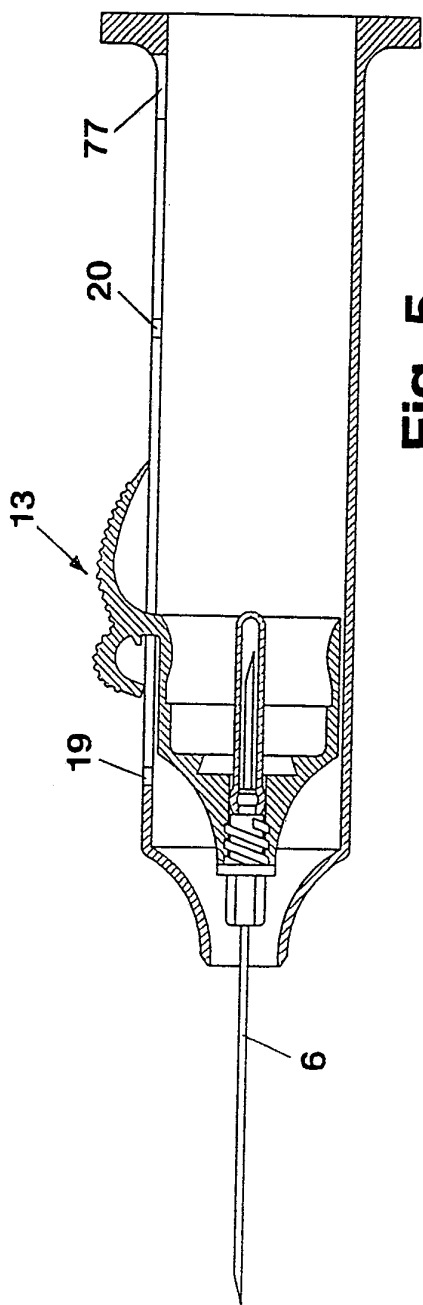


Fig. 5

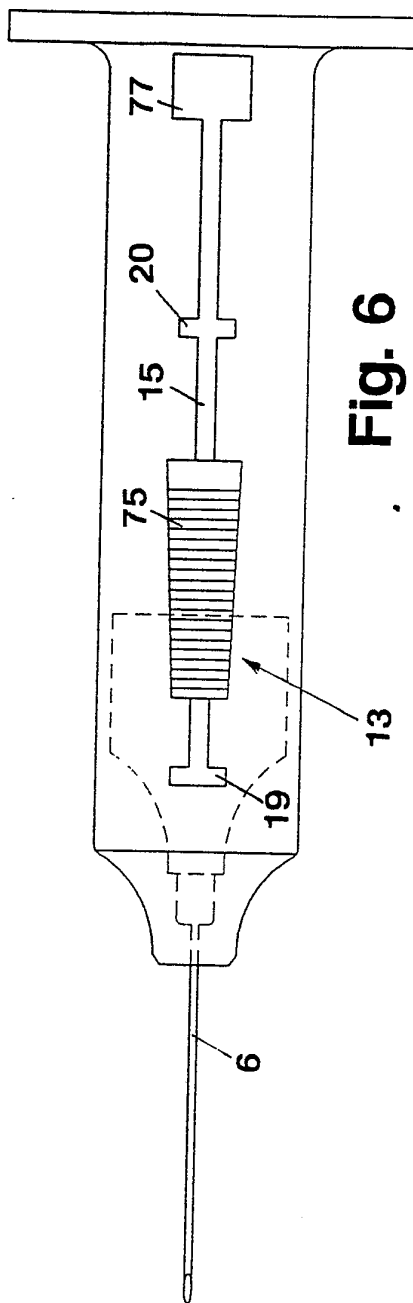


Fig. 6

4/6

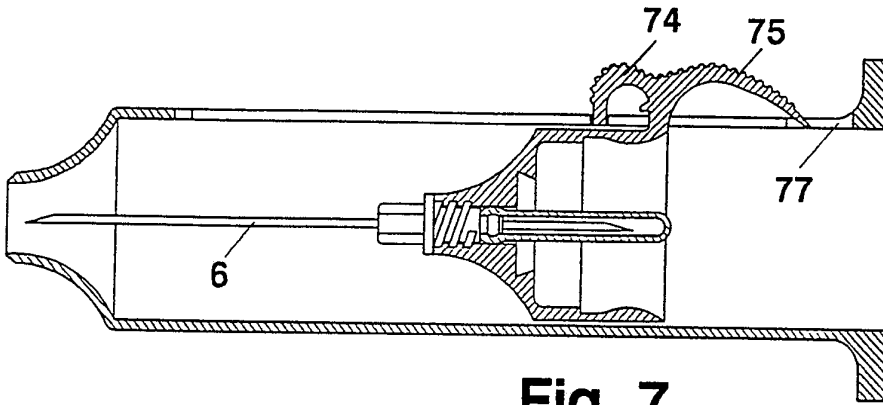


Fig. 7

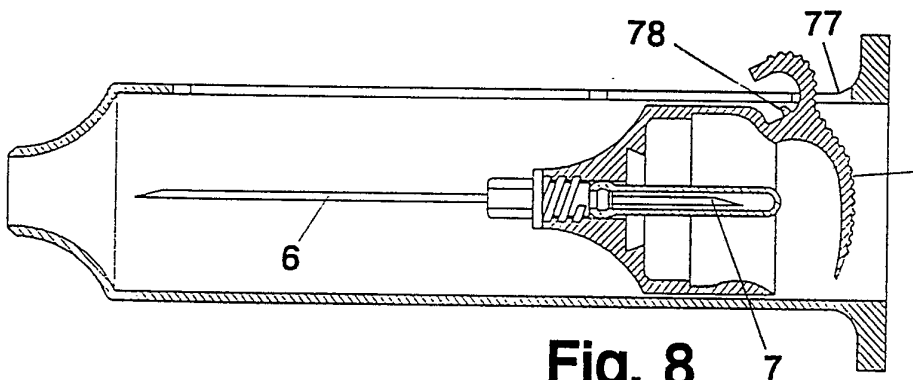


Fig. 8

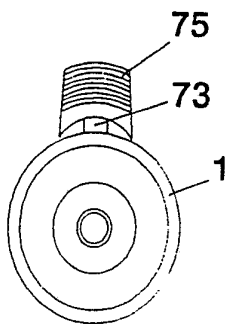


Fig. 10

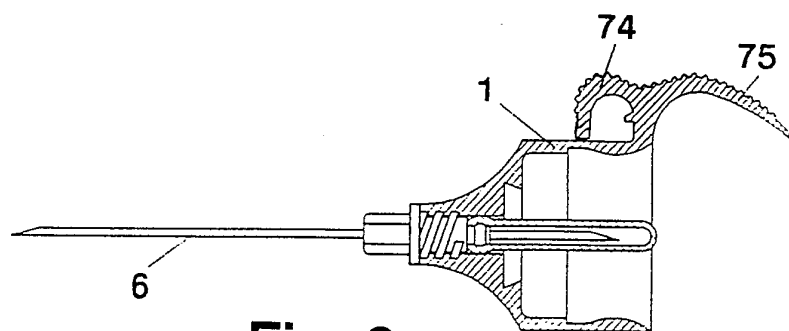


Fig. 9

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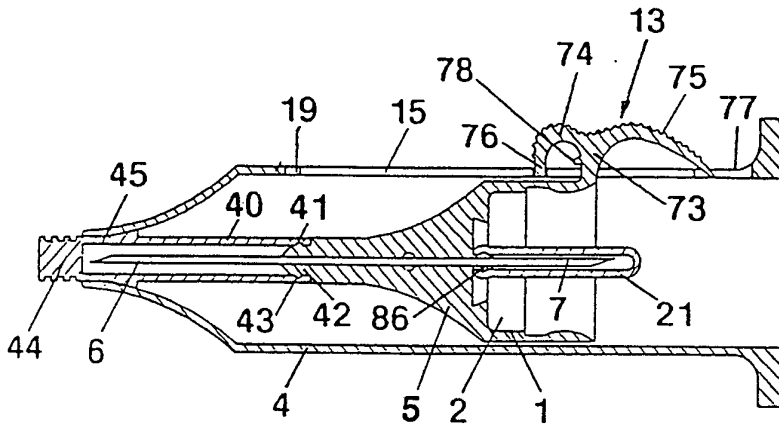


Fig. 13

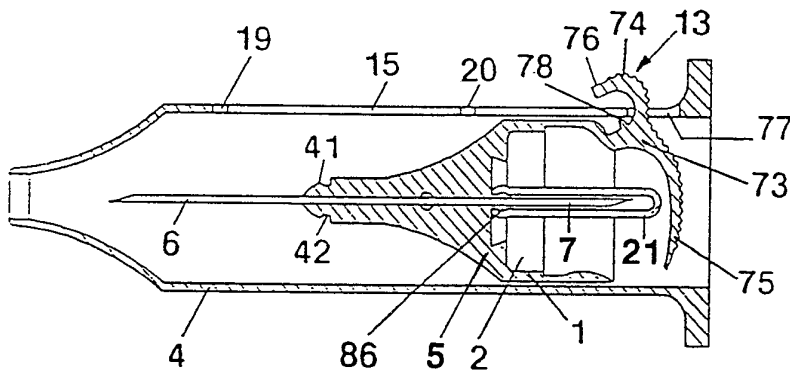


Fig. 14

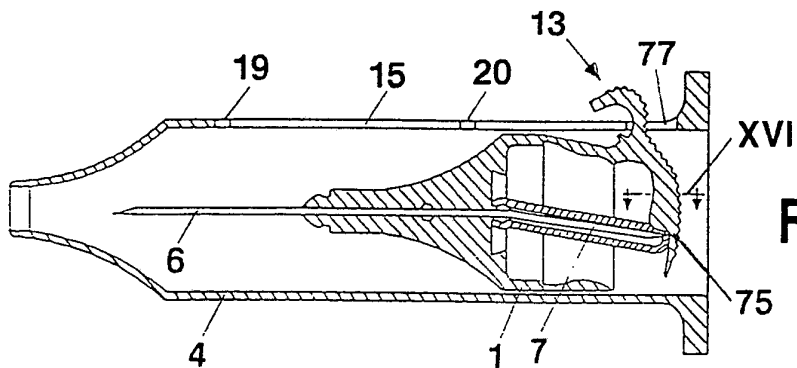


Fig. 15

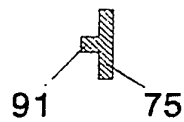
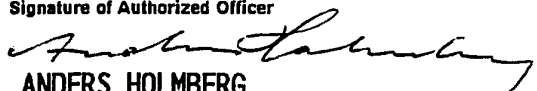


Fig. 16

INTERNATIONAL SEARCH REPORT

International Application No PCT/DK 92/00162

I. CLASSIFICATION OF SUBJECT MATTER (If several classification symbols apply, indicate all) ⁶				
According to International Patent Classification (IPC) or to both National Classification and IPC IPC5: A 61 B 5/14				
II. FIELDS SEARCHED				
Minimum Documentation Searched ⁷				
Classification System	Classification Symbols			
IPC5	A 61 B			
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in Fields Searched ⁸				
SE,DK,FI,NO classes as above				
III. DOCUMENTS CONSIDERED TO BE RELEVANT⁹				
Category *	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³		
Y	US, A, 4758231 (TERRY HABER ET AL) 19 July 1988, see column 7, line 48 - column 8, line 29; figures 7-9 --	1,2,6- 10		
Y	WO, A1, 9002515 (NORGÅRD, TINA) 22 March 1990, see page 13, line 12 - line 22; figure 7 --	1,2,6- 10		
Y	WO, A1, 8904141 (WEIBEL, STIG) 18 May 1989, see page 9, line 26 - line 37 --	1,2,6- 10		
A	US, A, 4846808 (TERRY HABER ET AL) 11 July 1989, see the whole document --	1-10		
<table style="width: 100%; border: none;"> <tr> <td style="width: 50%; border: none; vertical-align: top;"> <p>* Special categories of cited documents:¹⁰</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"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)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> </td> <td style="width: 50%; border: none; vertical-align: top;"> <p>"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</p> <p>"X" document of particular relevance, the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"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.</p> <p>"&" document member of the same patent family</p> </td> </tr> </table>			<p>* Special categories of cited documents:¹⁰</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"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)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p>	<p>"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</p> <p>"X" document of particular relevance, the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"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.</p> <p>"&" document member of the same patent family</p>
<p>* Special categories of cited documents:¹⁰</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"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)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p>	<p>"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</p> <p>"X" document of particular relevance, the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"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.</p> <p>"&" document member of the same patent family</p>			
IV. CERTIFICATION				
Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report			
12th August 1992	1992 -08- 21			
International Searching Authority	Signature of Authorized Officer			
SWEDISH PATENT OFFICE	 ANDERS HOLMBERG			

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)		
Category *	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No
A	US, A, 4892107 (TERRY M HABER) 9 January 1990, see the whole document --	1-10
A	US, A, 4900310 (GEORGE B. OGLE II) 13 February 1990, see the whole document --	1-10
A,P	US, A, 5030209 (ALAN A WANDERER ET AL) 9 July 1991, see the whole document --	1-10
A,P	US, A, 5070885 (JEAN M. BONALDO) 10 December 1991, see the whole document --	1-10
A,P	US, A, 5086780 (ROBERT J. SCHMITT) 11 February 1992, see the whole document -- -----	1-10

**ANNEX TO THE INTERNATIONAL SEARCH REPORT
ON INTERNATIONAL PATENT APPLICATION NO.PCT/DK 92/00162**

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the Swedish Patent Office EDP file on 01/07/92
The Swedish Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US-A- 4758231	88-07-19	EP-A- 0288879	88-11-02
		JP-A- 63317160	88-12-26
		US-E- RE33585	91-05-07
		US-A- 4790827	88-12-13
		US-A- 4892523	90-01-09
		US-A- 4915702	90-04-10
WO-A1- 9002515	90-03-22	NONE	
WO-A1- 8904141	89-05-18	AU-D- 2716788	89-06-01
		EP-A- 0386087	90-09-12
		JP-T- 3502648	91-06-20
US-A- 4846808	89-07-11	AU-D- 3000489	89-08-17
		EP-A- 0329038	89-08-23
		JP-A- 1249066	89-10-04
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US-A- 4900310	90-02-13	AU-D- 4123389	90-04-12
		EP-A- 0363180	90-04-11
		JP-A- 2211126	90-08-22
US-A- 5030209	91-07-09	NONE	
US-A- 5070885	91-12-10	NONE	
US-A- 5086780	92-02-11	NONE	