System for withdrawing blood

The present invention concerns a system for withdrawing body fluids from a part of the body in particular the finger pad by producing a small puncture wound.

In the field of clinical diagnostics it is necessary to obtain samples of body fluids, in particular blood samples, in order to detect constituents thereof. If a larger amount of blood is required, it is usually collected with a syringe or such like by piercing a particular blood vessel. However, the field of the present invention is one in which only small amounts of sample in the range of a few µl or less are necessary to determine analytical parameters. Such a procedure is especially widespread for measuring the blood sugar level and it is also used for example to determine coagulation parameters, triglycerides, HBA1c or lactate. In the field of diabetes it has now become accepted practice for diabetics to monitor their blood sugar level (so-called home-monitoring). This is necessary to set a blood sugar level which is within the normal range by administering calculated doses of insulin. If, in contrast, a diabetic becomes hypoglycaemic he may become unconscious and it may even result in the death of a patient. If, on the other hand, a patient has a blood sugar level which is too high, this can lead to serious secondary effects such as loss of sight and gangrene. Small and easy-to-handle blood withdrawal devices, so-called lancing aids that can be simply and reliably operated by the user or hospital and nursing staff are now commonly used to withdraw the blood required to measure the blood sugar level. Recently systems for withdrawing interstitial fluid have also been disclosed which can in principle be used to carry out such analyses.

An emerging problem in this field is contamination and injury by used lancets. In many commercial devices the lancet is removed or ejected after the lancing process. The needle of the lancet which is exposed in such cases can lead to injuries that may result in infections. Consequently in some countries attempts are already being made to prohibit blood withdrawal systems in which the needle tip is freely accessible after use.

Various variants of blood withdrawal systems have been described in documents of the prior art in which the needle is protected after the lancing process. A cap in which

a lancet is located is described in the document US 5,314,442. In order to carry out a lancing process, the lancet is pushed within the cap by a plunger or a similar device in such a manner that the needle exits through an opening. After the piercing the lancet is retracted inside the cap and flexible elements on the lancet ensure that the lancet needle can no longer emerge without the action of the plunger. Systems based on a similar principle are described in the US Patents 4,990,154 and 5,074,872 and the International Application WO 00/02482. Another system in which a lancet is retracted into a cap by an incorporated spring is described in the document DE 198 55 465. Although the said documents already solve the problem of contamination or injury to the user, the drive mechanism is only coupled to the lancet by a press fit. The puncture depth of the needle is limited by a stop. However, it has turned out that the lancet impacting on the stop vibrates the needle which increases the pain caused by the puncturing. This problem is described in more detail in EP 0 565 970.

The object of the present invention was to suggest a system for withdrawing body fluid, which, on the one hand, avoids contamination or infection by used lancets and, on the other hand, allows a substantially pain-reduced lancing for the user. Another object was to simplify the systems of the prior art and make them more cost-effective and in particular to propose a design which can be miniaturized. The latter is especially important in order to provide a system that operates with lancets in magazines and allows a user to change a lancet that has not yet been used without having to carry out complicated handling steps.

The said objects are achieved by embodiments of systems for withdrawing body fluid which have a drive unit with a plunger which is moved from a resting position into a lancing position in order to carry out a lancing process. The systems also comprise a lancing unit in which a lancet with a needle is located that, in the resting position of the plunger, is arranged within the lancing unit and is displaced by the plunger when it moves into the lancing position in such a manner that the needle at least partially emerges from the lancing unit through an outlet opening. An essential feature of the system is that the plunger and lancet are interconnected by a form fit in order to carry out the piercing process.

A characteristic feature of a form fit in the sense of this invention is that it enables the lancet and driving plunger to be coupled with little expenditure of force. There are two basic ways for achieving a form fit. In a first variant the lancet and driving plunger are coupled by close fitting in such a manner that a holding element is enclosed. The form which closes is referred to as a holding device within the scope of the invention. If the holding device is located on the lancet, the driving plunger has a holding element but if the holding device is on the driving plunger, the holding element is located on the lancet. Figures 1 and 2 shows practical embodiments. This variant of the form fit is preferably achieved in that a longitudinal movement in the piercing direction causes a transverse movement of the holding elements of a (initially opened) holding device which thereby close around a holding area. The holding element is preferably (at least partially) gripped from behind when the holding device closes in such a manner that the lancet is carried when the driving plunger is pulled back – at least until a possible opening of the holding device. Furthermore it is preferred that the geometry of the holding device and holding area match in such a manner that there is no tolerance or only a slight tolerance in the direction of the lancing movement after the form fit and the movement of the driving plunger in the lancing direction as well as in the opposite direction is converted without any tolerance into a movement of the lancet. This can be achieved when the longitudinal extension of the chamber in the closed holding device is identical to or only negligibly larger than the longitudinal extension of the holding area (see figure 1). In another embodiment of this variant the longitudinal extension of a recess in the holding area and holding elements on the holding device correspond in such a manner that transport in the lancing direction is possible without essentially any play (see figure 2).

In a second variant of the form fit the holding device and the holding area are essentially dimensionally stable and the holding area is enclosed by the holding device, the profiles of these two units moving into each other. Since the units are dimensionally stable, a complete enclosure is not possible and the profiles must be open to such an extent that they can be moved into each other. This joining movement (of at least one path component) is at right angles to the lancing direction resulting in a connection which is also essentially without any play in the lancing

direction (see figure 4). Finally coupling can also be achieved by a movement having components at right angles as well as parallel to the lancing direction (see figure 7).

The system according to the invention for withdrawing blood has a drive unit with a plunger which moves a lancet from a resting position into a lancing position. A number of drive mechanisms are known from the prior art that can be used in the field of blood withdrawal devices. In particular drive mechanisms are used on a large scale which obtain their energy from a previously tensioned spring. Drive units are preferably used within the scope of the present invention which enable a guided movement of the plunger and the lancet as a result of the form-fitting connection. A guided movement means that the lancet pierces the body over a predetermined path and is also removed from the body over a predetermined path-time course. In conventional systems of the prior art based on a combination of a spring and a stop the path-time course is influenced by numerous parameters such as manufacturing tolerances (frictional conditions in the system, strength of the spring) as well as the skin surface. It has turned out that a guided movement of the lancet for example by means of a guide block as described in EP 565 970 is advantageous with regard to the pain caused by the piercing. With regard to the drive unit reference is herewith made to the preferred drive mechanisms of EP 565 970 and US 4,924,879.

An important aspect of the invention is a lancing unit containing at least one lancet that can be removed from the drive unit. The lancing unit comprises a housing in which the lancet is arranged in a resting position. This prevents the lancet causing injury or being contaminated before or after use. The housing can be designed such that a single lancet is located therein or the housing can have the form of a magazine containing a plurality of lancets. Usually the lancets in a magazine are located in separate chambers to prevent contamination of unused lancets by ones that have already been used. The housing of the lancing unit is advantageously designed such that it can be attached to the drive unit. For this purpose the lancing unit can for example have the shape of a cap which is mounted on the drive unit. Such embodiments are described for example in the documents US 5,314,442, US 4,990,154 and US 5,074,872. Embodiments are also possible in which the lancing unit is permanently connected to the drive unit or is an integral component of the drive unit. This can be especially advantageous for systems with a magazine such that the

entire unit can be discarded after the magazine has been used. In the case of a lancing unit in the form of a magazine, it can for example have chambers arranged next to one another in which the lancets are located and the chambers are positioned successively relative to the drive unit such that the lancets can be coupled to the plunger of the drive unit. A magazine in the form of a barrel having chambers arranged parallel to the longitudinal axis of the barrel in which the lancets are located is also particularly advantageous. In a similar manner to a revolver barrel, such a magazine can be repeatedly attached to the drive unit.

Another requirement for the lancing unit is that the sterility of the lancets must be ensured over a long time period. The lancing unit can be sterilized by gamma irradiation which is commonly used in the prior art. In order to maintain the sterile conditions, the lancing unit can be sealed in an enclosing package for example a polyethylene bag. In another embodiment the openings of the lancing unit (for inserting the plunger and for the exit of the needle tip) can be closed by sealing foils. These can for example be detachable sealing foils that are removed by the user before use. However, thin foils can also be advantageously used which are pierced before use by the plunger or by the needle tip so that the user does not have to carry out additional handling steps. Such foils can be already manufactured as a part of the manufacturing process for the lancing unit which is usually an injection moulding process.

In another advantageous embodiment the needle tip is protected from contamination by an elastomer which is removed before the lancing or is pierced during the lancing process in order to expose the needle tip. Such a protection of the needle from contamination is described in the application WO 01/66010 to which reference is herewith made.

One or more lancets with a needle are located within the lancing unit. Apart from devices that may be present on the lancet that enable a form-fitting connection to a plunger, lancets can be used within the scope of this invention that are well-known in the prior art. Such a lancet usually has a main body made of plastic in which a metal needle is located. However, lancets without a separate main body are also possible (such as metal needles having a thickening at the rear end as a holding area).

An important aspect of the invention is that the plunger of the drive unit and the lancet for carrying out the lancing process are connected together by a form fit. In this respect the invention differs substantially from the prior art where the lancet and drive are mechanically coupled by means of a press fit (US 5,314,442, US 4,990,154, US 5,074,872), a locking device (WO 00/02482), by clamping (US 3,030,959) or by simple pressure (DE 198 55465). A form fit is characterized in that a mechanically reliable coupling occurs between the drive and the lancet without having to apply a substantial pressure on the lancet in the direction of the lancing movement. In the devices of the prior art which work with a press fit, a spring element (e.g. DE 198 55 465) or a retaining element (e.g. WO 00/02482) have to be provided in the cap which contains the lancet and this element is designed such that the lancet does not emerge from the cap when the lancing unit is coupled to the drive unit. However, spring elements in the lancing unit increase the manufacturing costs which is particularly serious since the lancing unit is a consumable. Furthermore the drive unit requires an additional force to overcome a retaining element which also leads to vibrations of the needle which have an adverse effect on the puncturing pain. In addition a guided movement which comprises a retraction of the lancet is problematic in systems which utilize a press fit since this can detach the press fit. Although the locking device described in WO 00/02482 solves this problem, it is difficult to accomplish technically. In particular it is difficult to establish such a locking device in a continuous manufacturing process since even slight variations in the material or the process conditions can result in a loss of the function of the device. Another disadvantage of the device described in WO 00/02482 is that the locking occurs in a path range which serves to puncture the body. The fluctuations in force occurring during the locking and the vibrations have a disadvantageous effect on the pain of incision. Another disadvantage of the device is that the needle remains in the body after the incision and is not actively retracted. The needle is only retracted when the cap is removed from the drive mechanism. In contrast a form fit between the driving plunger and lancet according to the present invention enables the plunger and lancet to be connected without having to apply a particular force in the direction of the puncture and moreover the form-fitting connection can be advantageously utilized to actively retract the needle after the incision. This ability to actively control the path-

time curve of the needle by means of the drive unit enables the lancing to be carried out with very little pain.

Force (F) – path (s) curves are shown schematically in figure 8 for the process of coupling the drive to the lancet for press-fitting (a), locking (b) and form-fitting (c). It can be seen that when using a press fit the force increases substantially until the lancet is released from the position in which it is held by a holding element or a spring. In the case of a locking device the force increases during the locking and decreases again after locking. In the case of a form fit only very small forces are necessary to move the holding elements together.

Another property of the form fit according to the invention becomes apparent in a comparison with the document US 3,030,959. In an apparatus according to this US Patent, needles which are arranged in a tube are held successively by a clamping device which is similar to a propelling pencil. In addition to the contamination problems caused by used needles which are not solved by this apparatus, it is apparent that the positioning of the needles in the axial direction (i.e. in the lancing direction) is not defined. In the same way as the length of the protruding pencil tip can be freely selected by the user in the case of a propelling pencil, in this case the axial positioning of the needle depends on the adjustment by the user. In contrast the lancet and drive unit have matching holding areas and holding devices in the case of a form fit. The geometric design of the holding area and holding device enables the axial positioning of the lancet to be defined and thus enables an exact control of the puncture depth. Thus the use of a form fit avoids a force peak in the axial direction when the lancet and driving plunger are coupled together and also enables an exact axial positioning. In the case of a form fit, a form (holding device) encloses another form (holding area). In this sense enclosing means a movement of parts of the device at right angles to the lancing direction and also alternatively a form fitting interlocking of two shaped bodies whose shape does not change. In a preferred embodiment the holding device is open and closes around the holding area when it is inserted into the holding device. This enclosing can occur in particular as a result of a longitudinal movement in which the longitudinal movement is converted into a movement of holding elements of the holding device having components that are at right angles to the longitudinal direction of movement. One method with practical

advantages of achieving this conversion of a longitudinal movement into a transverse movement is to insert or slide the holding device by means of the longitudinal movement into a tapered channel (e.g. into a sleeve) (see figure 1). In this connection tapered not only refers to continuously tapering channels but in general channels whose inner width decreases in the longitudinal direction. In this connection a channel does not have to be a body with a closed circumferential surface. If for example the holding device has two opposing hooks as shown in figure 1, it only requires two walls whose distance to one another decreases.

Another possibility is to close the holding device by releasing a tensioned state (see figure 2) which can for example be achieved by moving the holding device in a broadening channel.

The present invention is further elucidated by figures:

Figure 1: Cross-sectional view through a lancing unit having a holding device on the lancet.

Figure 2: Cross-sectional view through a section of the system having a holding device on the drive unit.

Figure 3: Cross-sectional view through the total system and operating steps.

Figure 4: Section of the system with a dimensionally stable holding device on the drive unit.

Figure 5: Magazine of lancing units.

Figure 6: System consisting of drive unit and lancing unit.

Figure 7: System having a dimensionally stable holding device.

Figure 8: Force-path diagram for various types of coupling.

Figure 9: Lancing unit with a sterile protection.

Figure 10. Barrel-shaped magazine.

Figure 1 shows a blood withdrawal system according to a first embodiment of the invention in the operating phases I, II and III. Figure 1 only shows partial aspects of the system. The figure does not show the drive unit for the plunger (10) nor the housing of the drive unit to which the lancing unit (20) is attached. The driving device described in EP 0 565 970 is particularly suitable as a drive unit for the plunger (10).

The phases shown in figure 1 show how the form-fitting coupling between the driving plunger (10) and the lancet (30) occurs and the actual lancing process. Two cross-sectional views along the longitudinal axis of the system in perpendicular planes are shown for each of the three phases. The left view of phase I shows that the lancet (30) is arranged within a sleeve (40). The lancet (30) shown has a main body manufactured from plastic and a needle (31) made of steel that is injection moulded therein. The end of the lancet facing away from the needle tip has a holding device comprising holding elements in the form of two hooks (32a, 32b). When the plunger (10) is inserted into the lancet, a thickened region at the front end of the plunger which serves as a holding area (11) passes between the hooks (32a, 32b) and finally strikes the rear end of the needle (phase II). It is also possible to allow the plunger to strike the main body of the lancet instead of the rear end of the needle. However, a direct contact with the needle is advantageous since the length of the needle can be very exactly controlled in the manufacturing process and hence an accurate control of the puncture depth is possible. As the plunger penetrates further it pushes the lancet within the sleeve (40) towards the exit opening (41) such that finally the tip of the needle protrudes beyond the exit opening and pierces a tissue lying underneath. The transition from phase II to phase III shows that the holding devices (32a, 32b) on the lancet close around the holding area (11) of the plunger as soon as the lancet is displaced within the sleeve (40). The holding device on the lancet grips around the holding element of the plunger in such a manner that a form-fitting connection is formed which not only enables a forwards movement of the lancet in order to carry out an incision but also an active retraction of the lancet controlled by the drive unit which is essentially without play. This is ensured on the one hand by the fact that the end of the holding area rests on the end of the needle and by the hooks (32a, 32b) which grip behind the rear end of the holding area. The length of the holding area

and the longitudinal extension of the chamber in the closed holding device are designed to match one another in such a manner that the lancet can be driven in the lancing direction without play. The arrangement of the lancet or the holding device in a tapered sleeve enables a longitudinal movement of the lancet in the lancing direction to be converted into a transverse movement of the elements of the holding device which enables a form fit with the holding area of the drive. The figures show that the sleeve (40) has a middle region (40b) which is tapered compared to the upper region (40a). As a result of this tapering the hooks (32a, 32b) of the lancet are pressed together when the lancet is moved in the sleeve in the direction of the longitudinal axis such that the holding area (11) is enclosed. It has proven to be particularly advantageous to design the lancing unit (20) such that the lancet is held within the sleeve when it is not acted upon by the plunger. This ensures that the needle is located within the sleeve (40) when it is not actuated and thus there is no injury or contamination caused by a protruding needle tip. The lancet is effectively prevented from sliding through the sleeve towards the exit opening (41) by the fact that the hooks (32a, 32b) have a shoulder which rests on an edge of the middle region (40b). The slope of these edges and the flexibility of the hooks can be matched in such a manner that an insertion into the tapered region can occur with a small force, but on the other hand, an unintentional sliding through is efficiently prevented. In order to prevent the lancet from sliding out of the sleeve in the opposite direction to the lancing direction, the embodiment shown provides a widened part (40c) at the lower end of the sleeve and a corresponding widened part (30a) at the lower end of the main lancet body.

As shown in figure III the needle tip is still within the sleeve (40) when the holding area (11) strikes the end of the needle. This is advantageous since the shock caused by the impact has no influence on the lancing process in the tissue which thus avoids incision pain caused by such a vibration.

According to the invention it is preferred that the system is designed such that after phases I, II and III are completed, the plunger (10) is retracted in the reverse direction such that the plunger is disconnected from the lancet and the lancet is again located completely within the sleeve. There are two main variants for coupling the plunger to the lancet. In a first variant, the housing, drive unit and lancing unit are

matched in such a manner that the plunger in the initial state is located completely outside the lancing unit (20) (as shown for phase I). A disadvantage of this embodiment is that the plunger has to travel through a relatively long path in order to carry out the piercing process. However, an advantage is that the plunger is located completely outside the sleeve such that a transverse movement is possible. Accordingly the first variant can be advantageously used for systems having a lancet magazine in which various sleeves are successively moved under the plunger. In a second variant the coupling of the lancing unit to the drive unit already results in a positioning according to phase II or even towards phase III. In such an embodiment the path which the plunger has to travel through can be kept very small which is technically advantageous for the construction.

Figure 2 shows a second embodiment of the invention in which the lancet (130) has a holding area (131) and the drive unit has a holding device (132a, 132b). Figure 2 also shows the area of the system which is used to hold the lancet but does not show the drive unit. In connection with this embodiment it is also advantageous to use a drive unit which moves the plunger (110) in a guided manner. The front end of the plunger carries a holding device comprising holding elements in the form of two hooks (132a, 132b) which are connected together by a flexible bridge (133) (or a joint). The arrangement forms a spring element. In phase I these hooks are spread since their rear ends are held together by a sleeve (140). When the lancet (130) is inserted, the sleeve is simultaneously pushed against a spring (141) which releases the rear ends of the hooks and the front ends of the hooks close around the holding area (131) of the lancet in a form-fitting manner. The holding area of the lancet has a recess (depressions) into which the hooks of the holding device engage. The longitudinal extension (in the lancing direction) of the engaging ends of the holding device and the longitudinal extension of the recesses are essentially identical so that this arrangement can be used to carry out a guided, essentially play-free lancing movement. Also in this embodiment a longitudinal movement of the holding device is converted into a transverse movement of the holding elements.

Figure 3 shows a system according to the invention based on the form-fitting coupling principle of figure 2. The drive unit (100) is based on the Softclix®

instrument which is described in EP B 0 565 970. This document shows in particular how the rotary movement of the sleeve (171) mediated by the drive spring (170) is converted into a translational movement of the plunger (110). The tensioning of the drive spring by depressing the pressure button (172) and a suitable mechanical transmission therefor are described in the European Patent Application with the file number EP 0 010 2503.0. The front end of the drive unit has a holding device comprising two holding elements, in this specific case hooks (132a, 132b). As already explained for figure 2, the hooks are connected together in a middle region via a flexible bridge (133) or a joint. On the side of the hook facing away from the bridge (133), the holding device is held by a sleeve (140) in such a manner that the hooks are opened. The sleeve (140) is kept in position by means of a spring (141) located in the driving device. Figure 3 I also shows a lancing unit where a lancet (130) is arranged in a cap (121). The rear end of the lancet has a holding area (131) which is gripped by the holding device (132a, 132b). The outer body of the lancet has a narrow region at the front and a flange (122) situated between this narrow region and the holding area (131). The tip of the lancet is protected from contamination and mechanical influences by a twist-off plastic body (123). The inside of the cap (121) has a passage for the narrow region of the lancet and a region with an enlarged cross-section which is suitable for receiving the flange (122). A bead (124) is located within this widened channel of the cap which prevents the flange from sliding through into the widened channel. The cap also has a sleeve (125) which serves to slide back the sleeve (140) of the drive unit when the lancing unit is placed on the drive unit. This process is illustrated by both figures 3I and 3II. When the sleeve (140) is pushed away by the sleeve (125),the holding device is released such that it can surround the holding area of the lancet as shown in figure 3II. The system is now prepared for use by pressing the button (172) and twisting off the protective part (123) of the lancet. A lancing process is then carried out with the device shown in figure 3II by placing the front end of the cap (120) on a part of a tissue and the drive unit is activated by actuating a trigger mechanism. After the lancing process is completed the cap is pulled from the drive unit in the direction of the longitudinal axis which retracts the flange (122) behind the bead (124) so that the contaminated needle tip can no longer emerge from the cap. In the stage shown in figure 3III, the lancing unit can be discarded or be used for further sampling processes after coupling to the drive unit.

Figure 4 shows a third embodiment of the invention in which the form fit between the lancet and drive is achieved by a form-fitting connection of geometrically matching holding areas and holding devices. Figure 4A shows a lancing unit (220) which has a sleeve (240) in which a metal needle (231) is located. The sleeve (240) has a thin cross wall (250) which holds the metal needle relative to the sleeve. This cross wall is preferably moulded at the same time as the needle is moulded into plastic. Due to the relatively small thickness of this wall, the mechanical connection between the sleeve and needle can be released during the lancing process such that the needle slides past the wall (250). The exit opening of the sleeve is closed with a thin foil (260) which is pierced during the lancing process. The upper end of the needle (231) carries an injection moulded holding area (232). For mechanical stabilization the needle has a taper around which the holding area (232) is injection moulded to prevent axial slipping. The needle can also be held in the sleeve by roughening the outer surface of the needle, or by means of a thickening or bend in the needle in the area of the sleeve. The driving plunger (210) of this embodiment has a holding device (211) at its lower end which embraces the holding area (232) in a form-fitting manner as shown. The side of the holding device (211) is open such that the plunger is displaced parallel to the needle and containing the holding device (211) can be moved to the level of the holding area (232) and can be engaged with the holding area of the needle by moving it at right angles to the axis of the needle or to the direction of lancing. After the form fit achieved in this manner, the needle can be propelled by the plunger (210) in the direction of lancing and also be actively retracted. In the example shown the holding area of the lancet has a recess (depression) into which a projecting part of the holding device engages during the coupling such that the two members are connected together without essentially any play in the direction of lancing.

A magazine is shown in figure 4B which is composed of lancing units (220) according to figure 4A. With reference to the coordinate system shown, the driving plunger (210) can engage with the holding area of the lancet or the form fit can be released again by movement in the Y direction (perpendicular to the plane of the drawing). When the form fit is released the driving plunger can be moved in the X direction (right/left) to the level of another lancet and in turn engage with this lancet by movement in the Y direction such that the lancets of a magazine can be successively

processed. After the form fit the needles can be actively moved in a positive as well as a negative Z direction (upwards/downwards).

As an alternative to the coupling according to figure 4B which requires a movement of the driving plunger in the X and in the Y direction, a coupling movement can also be accomplished by a movement in the X direction only. For this purpose the driving plunger for example has two opposing hooks between which a passage for the holding area of the lancet is provided. By movement in the X direction the plunger can now be moved from lancet to lancet in order to carry out a lancing process in the Z direction. If the driving plunger is at the level of a lancet in the X direction, the holding device of the plunger encloses the holding area of the lancet in a form-fitting manner and the lancet can be moved by the plunger in the Z direction in a guided manner; as a result the plunger carries out a lancing movement and also actively retracts the lancet.

Figure 5 shows an automated system containing lancing units according to figure 1. The top view (figure 5B) shows how the lancing units (20, 20' etc.) are attached next to one another on a conveyor belt. The conveyor belt (301) travels around two spaced apart rollers (302, 303). One of the rollers is driven by a motor such that the lancing units are successively moved through a coupling position (305). As shown in figure 4a a form-fitting coupling of a driving plunger (10) to a lancing unit (20) located in the lancing position (305) is possible in this position.

Figure 6 shows a drive unit to which a lancing unit like the embodiment shown in figure 1 is coupled. The drive system shown corresponds to the European Patent Application file number 00102503.0. In this drive system a sleeve (414) is axially rotated by pressing a press button (420) against the tension of a spring (418) such that a second spring (415) is tensioned. The sleeve (414) is locked in an end position such that the second spring (415) remains tensioned. When the user releases the locking device, the spring (415) relaxes and the sleeve (414) is rotated in the opposite direction to that of the tensioning process. A groove is located in the sleeve (414) which acts as a guide block for the propelling cylinder (408) which has a pin or similar means which engages in the groove. Hence the rotation of the sleeve (414) is converted into a translation of the propelling cylinder. The propelling cylinder

transfers its forwards movement to the driving plunger (480) which has a holding area at its front end.

The drive unit has a holding area (450) onto which a lancing unit can be mounted or screwed on. The lancing unit comprises a cap (470) which has a surface for pressing down on the skin surface. The cap contains a sleeve (471) which has a lancet (472) that has holding devices on the end facing away from the needle tip. The holding device of the lancet corresponds to the holding devices (32a, 32b) of figure 1. Figure 5 also shows that a form-fitting connection of the lancet and driving plunger is already accomplished by attaching the cap (470) to the driving device.

Figure 7 shows a system for withdrawing body fluids which has many similarities with the system shown in figure 3. Particular reference is made to the description of the drive and tensioning mechanism for figure 3 and figure 6. The system according to figure 7 has a lancing unit (120') with a cap (121') and a lancet (130'). There is an axial passage in the cap (121') through which the lancet body can pass during the lancing process. The passage and lancet body preferably match one another in such a manner that the lancet is guided axially during the lancing process with only a slight play in the transverse direction. The cap has a thread (126) at its rear end which can be screwed onto a corresponding thread (127) of the drive unit (100'). The end of the lancet opposite to the needle tip has one or more (in the case shown two) pins (131') which make a form fit with the holding device (132') when the cap is placed or screwed onto the drive unit. For this purpose the holding device has a recess or groove that has an axial member (134a) and a member (134b) arranged at right angles thereto. When the cap is placed on the drive unit the pins (131') come into the axial part of the groove (134) and move through this groove to the level of the transverse part of the groove. When the cap (120') is screwed onto the drive unit (100') the pin (131') moves from the end of the axial part into the transverse part of the groove up to the opposite end. As shown in figure 7 II the lancet is held axially by the holding device (132') by means of the pin such that a guided lancing movement can be carried out with the lancet. Due to the position of the pins in the transverse part of the grooves the lancet can be moved such that the needle tip emerges and is also retracted. As shown in figure 7 the form-fitting connection between the lancet

and holding device is achieved without wedging or locking. The coupling principle shown in figure 7 of the lancet and driving plunger can of course also be accomplished in a converse manner i.e. with a corresponding holding device of the lancet and a holding area on the plunger or drive.

Figure 9 shows a further development of the system of figure 1. The driving plunger (10′) has a holding area (11′) which has a circumferential slanted surface on its upper side which fits between the slanted surfaces of the hooks (32a′, 32b′) during the lancing process. The end of the driving plunger rests on the end of the needle while pressing together the flexible hooks (32a′, 32b′) causes the sloping surfaces on the inner side of the hooks to be pressed against sloping surfaces on the upper side of the holding area such that the holding area is pressed onto the end of the needle thus forming a play-free connection of the holding area and lancet in the direction of lancing. This fit results in a very precise interlock between the lancet and driving plunger which compensates for (manufacturing) tolerances and thus eliminates play during the lancing and return movement.

The holding device in the form of hooks (32a′, 32b′) is also designed such that the free ends of the hooks engage in recesses in the sleeve (40′). This prevents the lancet (30′) from accidentally slipping out of the sleeve (40′). As shown by the transition from figure 9A to figure 9B the free ends of the hooks are initially detached from the recesses at the beginning of the lancing process and the hooks are pressed together during insertion into the tapered sleeves such that they enclose the holding area of the driving plunger.

Figure 9 also shows that the needle tip (31′) is arranged in a material (35). This material (35) is preferably an elastomer which tightly encloses the needle tip to effectively prevent contamination of the needle tip. Suitable elastomers are styrene oligoblock copolymers, thermoplastic polyolefins, thermoplastic polyurethanes, thermoplastic copolyesters and thermoplastic copolyamides. Reference is herewith made to the international application WO 01/66010 with regard to further details of this procedure for preventing contamination of the lancet tip. In the initial position of figure A before lancing, the needle tip is located in the elastomer which is pierced

by the needle when a puncture is carried out as shown in figure B. For this purpose the underside of the sleeve (40') has a plate (36) with a central opening. The plate prevents the elastomer from emerging through the opening so that the elastomer is pierced when the needle passes through the central opening. When the lancet is retracted, the elastomer remains on the needle and the needle tip is now exposed (see figure C).

Figure 10 shows a cross-section (figure A) and a perspective view (figure B) of a cylindrical magazine based on lancets according to figure 1 and figure 9. Such a magazine enables new lancets to be coupled to the drive in a simple manner. For this purpose the driving plunger can for example be fixed relative to a lancing aid and the barrel-shaped magazine shown in figure 10 is rotated like a revolver barrel such that unused lancets are moved into the position for coupling to the driving plunger.

Claims

1. System for withdrawing body fluid comprising

a drive unit (100, 100') having a plunger (10, 110) which is moved from a resting position into a lancing position in order to carry out a lancing process and

a lancing unit (20, 120, 120') containing a lancet (30, 130, 130') with a needle which in the resting position of the plunger is arranged within the lancing unit and is displaced by the plunger when it moves into the lancing position in such a manner that the needle at least partially emerges through an exit opening (41, 41') in the lancing unit,

wherein the plunger and lancet are coupled together by a form fit in order to carry out a lancing process.

2. System as claimed in claim 1, in which the plunger has a holding area (11) which is held in a form-fitting manner by a holding device (32a, 32b) on the lancet.

3. System as claimed in claim 1, in which the lancet has a holding area (131) which is held in a form-fitting manner by a holding device (132a, 132b) on the plunger.

4. System as claimed in claim 2 or 3, in which a longitudinal movement of the holding device moves holding elements of the holding device transversely to the longitudinal direction such that the holding elements move towards one another and the holding elements at least partially close around the holding area.

5. System as claimed in one of the claims 1 to 4, in which the lancing unit contains a sleeve (40) in which the lancet is movably located.

6. System as claimed in claim 1 or 4, in which the holding device of the lancet or of the plunger has at least one movable element (32a, 32b) which is moved transversely when the lancet is moved within the sleeve towards the lancing position such that a form-fitting coupling of the plunger and lancet occurs.

7. System as claimed in claim 5 or 6, in which the sleeve has a channel in which the lancet is moved and the lancet has a taper by means of which the at least one movable element is moved transversely when the lancet is moved towards the lancing position.

8. System as claimed in one of the previous claims, in which the lancing unit is detachably attached to the drive unit.

9. System as claimed in claim 8, in which the plunger is coupled to the lancet in a form-fitting manner when the cap is attached to the drive unit.

10. System as claimed in claim 8 or 9, in which the plunger and lancet are disconnected when the lancing unit is removed from the drive unit.

11. System as claimed in claim 3 or 4, in which the holding device has at least two flexible elements which move towards one another when the plunger is coupled to the lancet.

12. System as claimed in claim 1, which has a device for adjusting the extent to which the needle emerges from the cap.

13. System as claimed in claim 1, which has a magazine containing a plurality of lancets which can be successively coupled to the plunger of the drive unit.

14. System as claimed in claim 4, in which the holding device has two or more holding elements (132a, 132b) which close when the lancing unit is placed on the drive unit such that the holding elements hold the holding area of the lancet.

15. System as claimed in claim 14, in which the holding elements are connected by a spring element which moves the holding elements towards one another.

16. System as claimed in claim 15, in which the holding elements can be tensioned by a tensioning element against the force of the spring elements so that they are opened and placing the lancing unit on the drive unit releases the tensioning element such that the holding elements move towards one another.

17. System as claimed in claim 1, in which a holding device is located on the lancet or on the driving plunger which has at least one groove (134a) in the axial direction of the lancet which is open at one end to enable insertion of one or more pins on the lancet or on the driving plunger and the other end of the groove (134b) merges into a groove at right angles to the axial direction.

18. Method for temporarily extending a needle from a device for withdrawing body fluid comprising the steps

- coupling a lancet (30, 130, 130') to a plunger (10, 110) of a drive unit in a form-fitting manner where either the plunger has a holding area (11) and the lancet has a holding device (32a, 32b) or the lancet has a holding area (131) and the plunger has a holding device (132a, 132b),

- moving the plunger from a resting position in which the needle of the lancet is located inside a lancing unit into a position in which the needle emerges from an exit opening of the lancing unit,

- moving the plunger back in order to retract the needle into the lancing unit.

19. Method as claimed in claim 18, in which the lancet is coupled to the drive unit by attaching the lancing unit to the drive unit.

20. Method as claimed in claim 18, in which the lancet and plunger are disconnected by removing the lancing unit from the drive unit.

21. Lancing unit (20) for attachment to a drive unit comprising

a lancet (30) having a needle and a holding device with holding elements (32a, 32b) to make a form-fitting connection with a plunger of the drive unit.

22. Lancing unit as claimed in claim 21 having a sleeve (40) in which the lancet is arranged wherein the sleeve has a taper by which means the holding device is at least partially closed when the lancet is inserted into the sleeve.

23. System for withdrawing body fluid comprising

a drive unit (100, 100′) having a plunger (10, 110) which is moved from a resting position into a lancing position in order to carry out a lancing process and

a lancing unit (20, 120, 120′) containing a lancet (30, 130, 130′) with a needle which in the resting position of the plunger is arranged within the lancing unit and is displaced by the plunger when it moves into the lancing position in such a manner that the needle at least partially emerges through an exit opening (41, 41′) in the lancing unit,

wherein in order to carry out the lancing process in a longitudinal direction the plunger and lancet are coupled together by a form fit by coupling a holding device (211) to a holding area (232) by a movement at right angles to the longitudinal direction.

24. System as claimed in claim 23 in which the holding device is dimensionally stable and has an opening to receive the holding area.