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Lancing aid comprising a lancet system that is protected against re-use

The invention concerns a lancet system that can be used in a lancing aid for withdrawing blood for diagnostic purposes. In a variety of diseases it is necessary to examine human blood for an analyte contained therein. In many cases this only requires the withdrawal of a small amount of blood in the form of a blood drop by producing a small puncture wound. A particularly important example of such a case is diabetes in which the glucose content of blood has to be examined at regular intervals. Blood may also for example be examined with regard to coagulation parameters, triglycerides, HbA1c or lactate. Blood lancet devices which consist of a lancing aid and a tailor-made replaceable lancet are usually used to produce the required puncture wounds. The housing of the lancet instrument contains a lancet holder in which one interchangeable lancet can be inserted. During the lancing operation the lancet holder is rapidly moved in a lancing direction by a lancet drive of the lancet which is also integrated into the lancing aid until the needle tip emerges from an exit opening provided at the front end of the lancing aid and produces a small puncture wound in the part of the body that is pressed against the front end. Afterwards the lancet holder containing the lancet is moved back in the opposite direction to lancing.

Small, easy-to-handle blood collection devices, so-called lancing aids that can be easily and reliably operated by the user and enable a part of the body to be lanced in an almost painless manner are now routinely used. In order to avoid infections especially in hospitals, the lancets are disposable elements intended for single use. After a lancet has been used once, the lancet is removed after the lancing operation or ejected from the device and discarded as refuse. In such a case the exposed needles in a refuse container may lead to injury during waste disposal resulting in a contamination of other persons by the used lancet. Such contamination may lead to infections and thus some countries are planning to impose a ban on blood collection systems in which the needle tip is freely accessible after use. In addition to a risk of

injury during waste disposal there is also a risk that a used lancet may be accidentally re-used. This is particularly relevant for hospitals in which a lancing aid is used for several patients since such inadvertence of the nursing staff could lead to a patient being contaminated with the blood of a previous patient.

In addition to the use of blood lancet devices by medical staff, lancing aids are also used by laymen in the so-called home-monitoring field. This is particularly the case for monitoring the treatment of diabetics. Thus it has been found in the treatment of diabetics that serious damage associated with diabetes such as loss of sight can be substantially reduced when the glucose concentration in the blood of the diabetic is determined frequently and up to five times daily and the insulin injection is exactly adjusted on the basis of these measurements. Lancing aids which enable the diabetic to carry out such a blood examination are used for home-monitoring in order to carry out such frequent measurements. The resulting requirements for a blood lancet device are a simple handling when inserting new lancets and a reliable ejection of used lancets in addition to a simple handling when triggering the lancing operation and a relatively painless puncture. Lancet replacement should on the one hand be as simple as possible and, on the other hand, ensure the utmost safety with regard to unintentional injury of the user or other persons. Although in the home-monitoring field it is conceivable that a lancet, once inserted, is used several times for lancing by the same user, even in this case an accidental re-use of an ejected lancet should be prevented once the user has decided to discard the lancet. Furthermore other persons in particular should be reliably protected from the discarded lancets for example during waste disposal.

In the prior art the tip of the needle is usually surrounded by a tip cover made of plastic when the lancet is inserted which allows a safe insertion of the lancet. When the lancet is inserted, the tip cover is removed to expose the sharp tip of the needle for the lancing operation (US 5,628,765). However, due to the exposed needle tip there is a risk of accidental injury and the tip may become damaged. The lancet is removed from the lancing aid after one or several lancing operations. This can either be carried out manually in which case there is a high risk of injury by the needle tip or by an automatic ejection mechanism.

A blood lancet device is disclosed in the patent EP 0 565 970 in which the lancet is ejected from the lancet holder by means of an ejecting rod. The user can operate the ejecting rod by pressing a corresponding button.

Furthermore an ejecting mechanism is described in the patent document US 4,442,836 where the needle is automatically released when the lancing aid is retensioned so that the used lancet is discarded after each lancing operation. Such ejecting mechanisms require a relatively high degree of additional engineering. Moreover multiple use of an already inserted lancet system is not possible which is, however, often desired by customers especially in the home-monitoring field. Another major disadvantage of the described prior art is that the needle tip is unprotected after the lancet has been ejected resulting in a risk of injury as described above.

In order to facilitate the safe removal of a used lancet, blood collection systems are also described in the prior art which ensure the needle tip is protected after ejecting the lancet. This is regarded as an important feature especially for elderly users or those that are handicapped by poor sight and shaking hands as a result of disease.

A protection of the needle tip is achieved in the prior art by integrating the lancet in a cap of the lancing aid such that the lancet and the housing cap together form a replaceable disposable unit. Such designs are described in the documents EP 0595148 and US 4,990,154, US 5,454,828 and DE 10053974. When the lancet is ejected by the user, the housing cap is placed over the needle tip so that the lancet surrounded by the cap can be subsequently discarded. Even if the needle tip is protected after ejection by the described mechanism, it is nevertheless possible for a careless user to reinsert a needle that has already been ejected once and carry out a new lancing operation. Consequently the user is instructed to recognize that the needle has already been used.

Only the document EP 0 630 609 discloses a mechanism which directly prevents reinsertion and thus re-use of a lancet that has been ejected once.

The described lancet device comprises a needle with a needle body which breaks when the needle is ejected from the lancing aid to prevent a reinsertion of the needle.

This prevents the user from re-using a contaminated needle. However, a disadvantage of the prior art is that the needle tip is unprotected after the needle has been ejected.

The object of the invention is to provide an easy-to-use lancing aid preferably for the home-monitoring field which prevents re-use of an already ejected lancet system and also ensures a protection from injury by the needle tip after the lancet system has been ejected. It should advantageously be possible to easily re-use a needle of a lancet system that has been inserted once.

The object is achieved by a lancing aid and a lancet system according to the independent claims. Preferred embodiments are derived from the dependent claims.

The invention concerns a lancet system and a lancing aid containing the lancet system. The lancing aid has a housing for inserting a lancet system. The housing also has an opening where the needle tip can emerge from the housing and a drive mechanism for carrying out a lancing operation. According to the invention the housing additionally has a holding element which can interact with a corresponding holding element of the lancet system as soon as the lancet system has been inserted in the lancing aid. The interaction between the holding elements enables the lancet system to be positioned in the housing at a defined site. An exact positioning of the lancet system is important especially with regard to the drive mechanism for the lancing aid since it is the only way in which the needle can be correctly coupled to the drive mechanism such that the needle can perform a lancing operation at high speed and almost without vibration. This enables a rapid and relatively painless puncture in the intended part of the body. In addition to the described holding element, the lancet system for the lancing aid comprises at least one needle with a tip which is suitable for producing an opening in the skin. The needle is connected to a needle body and at least one protective portion of the needle body and the needle can be removed relative to one another. In a first position the needle tip is at least partially surrounded by the protective portion of the needle body whereas in a second position the protective portion of the needle body and the needle tip are disposed relative to one another such that the needle tip is released from the protective portion of the needle body. If the protective portion of the needle body is in its first position, it thus

guards against injury by the lancet tip which is particularly important after the lancet system has been ejected from the lancing aid.

The needle body also contains a blocking mechanism which is activated by an interaction with the lancing aid. The blocking mechanism changes the needle body in such a manner that after the lancet system has been ejected from the lancing aid, the holding element on the lancing aid can no longer interact with the holding element of the lancing aid when it is reinserted. This prevents re-use of a lancet system that has been ejected once. In this connection the blocking mechanism can be automatically actuated as soon as certain operating steps have been carried out on the lancing aid. However, other embodiments are conceivable in which the user actuates the blocking mechanism by a separate operating step.

As a result of the special design of the needle body, the lancet system according to the invention provides a protection from the needle tip such that after ejection from the lancet system the tip is surrounded by the protective portion of the needle body to such an extent that injury by the tip is prevented. The blocking mechanism also influences the interaction of the holding elements. Within the scope of the invention the term interaction of the holding elements encompasses any conceivable embodiment that is known in the prior art for inserting and positioning a lancet or a magazine in a lancing aid. For example the holding elements can be snapped in or clamped. Suitable holding elements for this may for example be designed as locking lugs, grooves or hooks to name only a few possible embodiments. Similarly to the systems described in the prior art containing individual lancets, it is also conceivable that the lancet system is already adequately positioned and held in the lancing aid due to its coupling to the drive unit so that for example the drive unit itself can be used as a holding element for an appropriately designed lancet system.

If several holding elements are provided to position the lancet system, the blocking mechanism advantageously prevents an interaction between the holding elements of the lancet system and the lancing aid so that the lancet system cannot be held and positioned in the lancing aid. This is particularly advantageous when the lancet system and lancing aid each have several holding elements that act independently of one another.

In a preferred embodiment the interaction of the holding elements is blocked in such a manner that the lancet system is prevented from being reinserted in the lancing aid. Within the scope of the invention the term "reinsertion" encompasses a handling of the lancet system such that the lancet system is positioned at the position in the lancing aid intended for carrying out the lancing operation and is held there due to the interaction of the holding elements. For this purpose the lancet system is again used at its original position in the lancing aid thus restoring the original state of the lancet system and lancing aid which was present when the lancing aid was first used.

When operating the lancing aid, the user can advantageously immediately and unambiguously identify an already used lancet system for example due to the fact that a reinsertion of the lancet magazine into the lancing aid is blocked. Hence in contrast to the prior art the user is not required to consciously distinguish between a used lancet system and a new lancet system. Advantageously the user is spared an unnecessary reinsertion of a used lancet system which no longer functions which elderly and visually handicapped persons often find to be difficult.

However, it is also possible that the blocking mechanism only blocks the lancing operation in which case it is possible to reinsert a needle that has already been ejected. If a reinsertion of the lancet system is prevented, this usually means that the lancet system cannot couple to the drive unit.

In a preferred embodiment the blocking mechanism is essentially achieved by a change in the shape of the needle body. This proves to be particularly advantageous when the shape of the needle body itself forms at least a part of a holding element. It is also possible that a deformation of the needle body spatially separates the holding elements in the lancing aid such that the blocking mechanism has an indirect effect on a holding element without directly acting on it. Hence the lancet system can no longer be positioned and held at a defined position in the lancing aid. In a preferred embodiment the deformation of the needle body transfers the protective portion of the needle body to a first position such that there is no risk of injury when disposing a used lancet. The protective portion of the needle body and the blocking mechanism are then achieved as a single component of the lancet system.

In principle the holding elements can interact in a variety of ways. The blocking mechanism may have a direct or indirect effect on the holding elements. In the case of a direct effect on the holding elements, at least one holding element is advantageously changed, covered or destroyed in such a manner that interaction of the holding elements is no longer possible. Furthermore embodiments are also conceivable in which the lancet system is positioned within a lancing aid due to magnetic properties of the system. Hence a change in the magnetic properties of the needle body could prevent a re-use of the lancet system. Appropriate magnetic elements of the needle body or lancing aid are then the holding elements of the system.

Since the blocking mechanism advantageously only prevents a repeated insertion of the lancet system but does not prevent re-use of a needle that has already been inserted, the lancet system also satisfies requirements in the home-monitoring field where multiple use of a once inserted needle is often desired.

The lancing aid according to the invention for collecting blood has a drive unit with a plunger which moves a needle from its resting position into a lancing position. A number of drive mechanisms are known in the prior art that can be used in the field of blood collection devices (e.g. US 5,314,442, WO 00/02482, US 3,030,959). In particular drive mechanisms are frequently used which draw 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 needle for example as a result of a form-fitting coupling as described in the document DE 10053974. Guided movements of the needle for example by means of guide blocks have also been previously described in EP 0 565 970. Such drive mechanisms are preferred because the puncture is less painful. However, the system according to the invention is not limited to a particular drive mechanism, but on the contrary, can be combined with a variety of drive units.

An important aspect of the invention is a lancet system that can be detached from the drive unit containing at least one needle where the lancet system is provided as a disposable unit. In this connection the term needle encompasses a blade-shaped substantially flat lancing unit and all other conceivable embodiments thereof. In

principle needles can be used for the invention that are basically well-known in the prior art and can be used in a lancet system. In the prior art a needle is often combined with a base body that can couple to the lancing aid which is referred to as a lancet. Such lancets often have a base body made of plastic in which a metal needle is disposed. According to the invention it is possible to integrate such a lancet into the lancet system according to the invention. It is for example conceivable that the needle body according to the invention contains a base body like that used for lancets in the prior art, where the inventive functionality of the system is maintained by integration of the base body. In this case the needle body has an at least two-part design according to the described embodiment. In a preferred embodiment the needle body is designed such that a plurality of lancets is disposed in the needle body such that the needle body represents a magazine containing a plurality of lancets and each base body of the lancet represents a part of the needle body. Consequently in a preferred embodiment the protective portion of the needle body is formed by the magazine housing. The needle and the base body can then be guided in a movable manner within the magazine. The needles within a needle body designed according to the invention as a magazine are preferably present in separate chambers in order to prevent contamination of unused needles by used needles when reloading.

In order to carry out a lancing operation, portions of the needle body are advantageously designed like the system already described in DE 10053974 such that the individual needles of the system can be actively coupled to the drive unit of the lancing aid. Embodiments that can also be used to drive needles within a magazine of a lancing aid are described for example in the documents DE 10053974, US 4,990,154 and US 5,074,872. The chambers arranged next to one another in which the lancets are individually located are positioned successively relative to the drive unit in order to carry out a lancing operation in such a manner that in each case a single needle can be coupled to the plunger of the drive unit. Also in this case magazines in the form of a drum containing chambers in which the needles are located parallel to the longitudinal axis of the drum have also proven to be particularly advantageous.

The lancet system also advantageously comprises a needle body which at least partially surrounds the needle tip by the protective portion of the body when the needle is in its resting position. In order to carry out the lancing operation, the

protective portion of the needle body is spatially separated from the needle tip so that the protective portion of the needle body does not hinder the lancing operation. When the lancet system is ejected from the lancing aid the needle remains in its resting position so that the ejected needle tip is protected and additionally the blocking mechanism according to the invention prevents a re-use of the lancet system. It is, however, also possible that the protective portion of the needle body is not transferred to its first position until the lancet system is ejected so that the needle tip is only protected as a result of the ejection. In a preferred embodiment an unused needle is also in a resting position before insertion into the lancing aid to prevent injury by the needle tip and contamination when the needle is inserted as well as after ejection.

A blocking mechanism according to the invention can be actuated for example when the lancet system is ejected from or inserted into the lancing aid independently of the needle tip protection. In principle the blocking mechanism or the needle tip guards can also be activated separately or by means of individual operating steps of the lancing aid e.g. during the lancing operation. In general all possible combinations are conceivable which ensure a simultaneous or successive blocking mechanism and protection of the needle tip.

The blocking mechanism can have a variety of designs but it is advantageous that the shape of the needle body is changed in such a manner that it is no longer possible to reinsert a lancet system once it has been ejected. For example the blocking mechanism can move at least one part of the needle body that interacts with the lancing aid in such a manner that a change in its position blocks a reinsertion of the lancet system. This is for example the case when the blocking mechanism closes a recess in the needle body which forms a holding element or a recess is generated in the needle body that is essential for an interaction of the lancet system with a lancing aid. Furthermore it is also possible that the blocking mechanism comprises a predetermined breaking point which results in a breaking of the needle body when the lancet system is ejected. It is also conceivable that the needle body is enlarged, made smaller or bent which are only a few methods for deforming the needle body.

According to the invention an interaction between the lancet system and lancing aid activates the blocking mechanism and sets a first position of the protective portion where the protective portion at least partially surrounds the needle tip.

An important requirement for the lancet system is that the needle tip that is used to produce a wound in an appropriate part of the body is sterile. The sterility of the needle tip has to be ensured over a long period which extends from the manufacture of the lancet system up to its use. Sterility can be achieved during the manufacture of the lancet system by for example gamma radiation which is commonly used in the prior art. In order to maintain sterility, the lancet system can be sealed in a wrapping, for example a polyethylene bag. In another embodiment the opening of the lancet system where the needle tip emerges from the protective portion of the needle body can for example be closed by a sealing foil. These are preferably detachable sealing foils which the user removes before using the lancet system. However, it is also possible to use thin foils which are not pierced by the needle tip until the needle is used so that the user does not have to carry out additional handling steps. Such foils may already be used as an integral part of the manufacturing process for the lancet system which is usually by means of an injection moulding process.

Furthermore in the prior art an elastomer is described in the application WO 01/66010 for sterile protection which encloses the needle tip and thus protects it against contamination. This sterile protection can either be pierced during the lancing operation or be removed by the operator before use.

In another advantageous embodiment the protective portion of the needle body can comprise a sterile protection and/or the protective portion can be essentially formed thereby. In this case the elastomer of the sterile protection serves for example as the protective portion of the needle body by the fact that the needle tip can be moved in a guided manner relative to the elastomer. Another part of the needle body that can be actuated independently of the sterile protection is able to change the needle body and represents the blocking mechanism. This requires that the sterile protection can reversibly expose the needle tip and surround it again which is for example the case with an elastomer protection (WO 01/66010) in which the elastomer is firstly pierced during the lancing operation and subsequently the needle tip is retracted into the

elastomer. Consequently in this example the needle tip changes its position relative to the sterile protection during the lancing operation and the needle tip is protected by the sterile protection in its resting position after the lancing operation. In principle many embodiments of a sterile protection are conceivable and hence the inventive system is not limited to any special embodiment of a sterile protection.

The system according to the invention is illustrated in the following on the basis of the figures and examples without being thereby limited to the individual examples.

Figure 1: Two-part lancet system

Figure 2: Lancet system in which the blocking mechanism is activated during the lancing operation.

Figure 3: Lancet system with a blocking mechanism that is activated when the system is ejected.

Figure 4: Lancet system with a blocking mechanism which prevents a lancing aid from coupling to the lancet system.

Figure 5: Lancet system with a blocking mechanism which is activated when it is inserted in the lancing aid.

Figure 6: Lancing aid with a lancet magazine.

Figure 7. Lancet system with a blocking mechanism which widens the needle body.

Figure 1 shows a lancet system (1) which is essentially in two parts. Figures 1b and 1d each show a cross-section through the lancet system shown in figure 1a and 1c before and after use respectively. The system has a needle (3), the front tip of which is wrapped in a sterile manner with an elastomeric protection (4). Such elastomers which ensure the sterility of the needle tip are known for example from the document WO 01/66010 to which reference is herewith made. The metallic needle (3) is attached to a plastic body (2b) and is permanently connected thereto. The plastic body has a rear portion (6) which couples the lancet system to a drive plunger such that the needle can be moved along the axis (8) in the direction of lancing. The rear

portion (6) of the plastic body which is a part of the needle body comprises two arms which can connect in a form fitting manner during the lancing operation with a drive plunger of a lancing aid (not shown) by means of the projecting parts (11). A form-fitting connection between a drive plunger and lancet is described for example in the document DE 10053974 to which reference is also herewith made. Of course any other coupling mechanism that is described in the prior art is conceivable for carrying out the lancing operation. The needle (3) and the plastic body (2b) that is permanently connected thereto are movably mounted in the plastic body (2a) which represents the protective portion of the needle body. The needle and the second part of the needle body (2b) can be moved within this needle body along the direction of lancing. The protective portion of the needle body (2a) has a lower wall (10) which has a hole (9) through which the needle tip can emerge during the lancing operation. The needle body also has an opening (7) at its upper end through which a drive plunger of a lancing aid can be inserted into the needle body in order to connect in a form-fitting manner with the second part of the needle body and perform the lancing operation. The protective portion of the needle body (2a) also has two recesses (13 and 14) which allow it to be locked into the second part of the needle body (2b). In order to enable the second part of the needle body to engage in the protective portion, the rear portion (6) of the second part of the needle body also has locking lugs (12) which engage in the recesses (14) in a first resting position of the lancet system before use and hold the second part of the needle body due to the spread arms (6). The middle portion of the protective portion and of the second part of the needle body have trough-shaped taper (5 and 5') of the body such that the tapered parts (5 and 5') exactly fit together in the first resting state before the lancet system is used and the lancet system in this position has the design shown in figure 1a.

In order to carry out the lancing operation, a plunger (not shown) of the lancing aid engages through the opening (7) into the lancet system where the plunger connects in a form-fitting manner with the arms (6) of the second part of the needle body. As a result the arms (6) are pressed together so that the lugs (12) of the arms (6) no longer engage in the recesses (14) and the needle can be moved forwards along the lancing direction (8). In this process the elastomeric protection (4) is firstly pressed against the lower wall (10) of the needle body (2a). If the lancing operation is continued the

needle is driven through the elastomeric protection and can thus emerge from the opening (9) in the lower wall (10) and produce a wound in the intended part of the body. The elastomeric protection (4) is meanwhile held back by the wall (10) as a result of which the front part (15) of the second part of the needle body (2b) corresponding to the recess (16) can move over the elastomeric protection. After the lancing operation has been carried out, the needle body (2b) and the needle are subsequently retracted into the protective portion (2a) due to the form-fitting coupling to the drive plunger. Once the rear arms (6) are in the rear protective portion of the needle body (2a), the lugs (12) can engage in the recess (13) of the needle body (2a) when the needle body (2b) is pulled back. The lancet system is now in a second resting position after the lancing operation. In this position the second part of the needle body (2b) protrudes from the opening (5) of the protective portion of the needle body (2a) in such a manner that the needle body is deformed in this area. The tapered parts (5 and 5') no longer fit together. In a lancing aid designed in a corresponding manner which only allows insertion of a lancet system when the tapered part (5) of the needle body is completely formed according to figure 1a, insertion of an already used lancet system is blocked according to figure 1c.

The example shown in figure 1 has a blocking mechanism and enables the protective portion of the needle body to be transferred to a first position during the lancing operation. When the lancet system is ejected after the needles have been used, the shape of the system has already been changed in such a manner that it is no longer possible to reinsert the lancet system in an appropriately designed lancing aid. Furthermore the needle tip is completely surrounded by the protective portion and hence there is no risk of injury for other persons e.g. during waste disposal.

Figure 2 shows a lancet system in the form of an essentially round lancet magazine. In comparison with figure 1 the protective portion of the needle body (2a) is only designed as a magazine so that a plurality of needles (3) can be movably guided therein.

Figure 2a shows an outer view of a magazine. The magazine housing which forms the protective portion of the needle body is designed similarly to figure 1 and has recesses (13 and 14) into each of which the locking lugs (12) of the respective second part of

the needle body (2b) can engage. The lancet system has a magazine axis (21) that is arranged concentrically in the protective portion of the needle body and is used as a bearing for the lancet system in a lancing aid. The lancet system can be rotated around the axis (21) so that one needle in each case can be positioned relative to a drive unit (not shown) in the lancing aid. Like the lancet system shown in figure 1, the lancet system in figure 2 also has tapered parts (5) within the protective portion of the needle body (2a) which are in the form of openings where the openings are also essentially tightly closed by the second part of the needle body (2b).

Figure 2b shows a cross-section through the lancet magazine shown in figure 2a. The system has a similar structure to that of figure 1, but consists of a plurality of needles that are equipped with an associated second part of the needle body (2b). Consequently the lancet system shown in figure 2 has several parts which include an outer protective portion of the needle body and several second parts (2b) of the needle body. Figures 2c and 2d show the lancet system after use in which all needles of the lancet system have already been used for lancing. It is of course also possible that only some of the needles have already been used in the lancet system. In this case the second part (2b) of the needle body would only protrude through some of the openings (5) of the protective portion of the needle body (2a) whereas the other openings would be tightly closed by the needle body as shown in figure 2a. Depending on how the lancet system interacts with the lancing aid, embodiments are conceivable where reinsertion of the lancet system into a lancing aid is already blocked as soon as some of the needles have been used or is only blocked after all needles have been completely used in the lancet system. Advantageously it is also conceivable that the reinsertion of a partially used lancet system into the lancing aid is only possible when the system has been positioned relative to the drive plunger in such a manner that only unused lancets can be used by the system.

Figure 3 shows a rectangular needle body which also comprises a plurality of needles in the form of a magazine. The protective portion of the needle body (2a) also has openings (9) in its lower end (10) from which the needles can emerge to perform a lancing operation. While in their resting position i.e. when no lancing operation is carried out, the needle tips of the needles (not shown) are within the protective portion of the needle body (2a) in which the needles can be movably guided. The

needle body (2a) contains grooves in a lower portion (34) that borders the lower end (10) of the needle body which make it easier to grip and thus facilitate its handling by the user. Recesses (33) are provided in this portion (34) as holding elements which, in an appropriately designed lancing aid, enable the lancet system to lock into the lancing aid during insertion. The blocking mechanism (31) is located in the middle of the needle body (2a) as part of the needle body (2a) and can be movably guided to an upper portion (35) of the needle body (2a), and is firstly held in a starting position by spring-mounted arms (39). There is also a recess (32) in the upper part (35) which locks the blocking mechanism (31) when the blocking mechanism (31) is guided along the upper part of the needle body (35).

Figure 3b shows the lancet system after use. As illustrated in figure 3b, the blocking mechanism (31) that surrounds the needle body (2a) in the form of a ring is now positioned at the upper end of the needle body so that the blocking mechanism (31) in this position widens the needle body section (35). Once the blocking mechanism (31) has been locked into its position, it is no longer subsequently possible to reinsert the lancet system due to the enlarged needle body.

Figures 3c and 3d illustrate in more detail the operation of the blocking mechanism (31) which is used in the lancet system described above. In order to lock the blocking mechanism (31) in the upper portion (35), the blocking mechanism has locking arms (36) which engage in the recesses (32). In the position shown in figures 3b and c the locking arms (36) are spring-mounted against the lower edge of the recess (32) to secure the blocking mechanism (31) against displacement. The stop (37) also serves as an additional counter-flange of the blocking mechanism (31) against the projection (38) in the upper portion of the needle body component (35). When the magazine is inserted as shown in figure 3e for first use in a lancing aid housing (70), the rear portion (35) of the magazine housing is positioned in an appropriately tapered position (82) of the housing (70). In contrast the front portion (80) of the housing (70) is widened so that the widened diameter of the lancet system due to the ring that acts as the blocking mechanism can be placed accordingly in the lancing aid housing. In this position the lancet system is held in the lancing aid in such a manner that a drive unit (not shown) of the lancing aid can engage in the magazine housing in order to couple onto a needle of the lancet system. The lancing aid housing also

has two stops (83, 84) which are adjacent to the blocking mechanism (31) in this position of the lancet system in the lancing aid. If the lancet system is removed from the lancing aid housing after use, the stop (84) firstly has the effect that the blocking mechanism (31) remains fixed in position in the lancing aid housing while the magazine housing is pulled out of area (82) of the lancing aid. As a result the blocking mechanism (31) is pushed along the needle body to the upper portion (35) of the needle body. In this process the blocking mechanism (31) locks with the needle body and the projection (38) and the stop (37) block further movement of the blocking mechanism along the needle body. If the blocking mechanism (31) rests against the projection (38), a further pulling movement on the magazine housing overcomes the resistance of the stop (84) and the magazine can be removed from the lancing aid. The magazine is now outside the housing in a used state as shown in figure 3b where the blocking mechanism (31) is permanently positioned on the needle body due to the locking hooks (36) and the stop (37). If the lancet magazine is reinserted into the lancing aid housing, the magazine can no longer be pushed into the tapered area (82) of the lancing aid due to the widened circumference of the upper section (35) of the needle body. Hence it is no longer possible to position the lancet system in its original position in the lancing aid. The lancet system can no longer be held in the lancing aid. The coupling of individual needles to the drive unit of the lancing aid in order to carry out a lancing operation is blocked. Moreover after the lancet system has been ejected, the user can easily visually recognize that the lancet system is a used system due to the displaced ring. For this purpose it is also conceivable that the blocking mechanism (31) is highlighted in colour.

As an alternative to the described change in the needle body (2a), it is for example also conceivable that the blocking mechanism (31) can be moved over the recesses (33) of the lancet system. In this case a reinsertion of the lancet system in a lancing aid would be prevented because the lancet system could no longer lock into the lancing aid. Other embodiments using a movably mounted blocking mechanism are conceivable which for example result in a reduction in the size of the upper section (35) of the needle body. In this case an unused lancet system e.g. in the state shown in figure 3b, is firstly placed in a lancing aid. A used lancet system would then be characterized in that the blocking mechanism (31) would have been pushed over the

needle body portion (35) in such a manner that the upper section (35) of the needle body (2a) is diminished in size. Figure 3a would thus represent the ejected state of the system. A correspondingly designed lancing aid would then for example have holding elements that could no longer interact with a lancet system that has been changed in this manner and reinsertion into the lancet system would no longer be possible. The locking elements of the blocking mechanism and of the needle body (2a) would then have to be adapted accordingly. Furthermore it is also conceivable that a movable blocking mechanism (31) ensures that a reinsertion of the lancet system is blocked and also protects the needle tips. In this case the needle tips would not, as shown in figure 3, be retracted into a protective portion of the needle body after the lancing operation. Hence the needle tips would not be automatically protected in a resting position. For example protection from the needle tips would not be ensured until the lancet system has been ejected from the lancing aid. According to the blocking mechanism shown in figure 3a, a movement of the blocking mechanism (31) elongates the needle body in the area of the needle tips so that the needle tips are surrounded in a protective manner by the blocking mechanism and at the same time the blocking mechanism is activated due to a change in the shape of the body. In this case a part of the needle body acts as a blocking mechanism and also as a protective portion of the needle body which surrounds the needle tip area when the lancet system is ejected. The protective portion of the needle body and the blocking mechanism then comprise one structural element of the needle body.

Figure 4 shows a rectangular lancet system in which several needles are positioned in chambers (42) of the protective portion of the needle body (2a). The upper section of the protective portion of the needle body has a blocking mechanism (41) in the form of a button which is located above the protective portion of the needle body and can be moved along direction (45) towards the protective portion of the needle body. The upper part of the button has a guide groove (49) which engages in a matching lip of the lancing aid (not shown) so that the lancet system can be securely positioned in the lancing aid. Once positioned in this manner, a drive plunger of the lancing aid (not shown) can couple with the rear area (48) of the needle (3) to carry out a lancing operation. For this purpose the needle is moved along direction (43) relative to the protective portion of the needle body and the needle tip emerges from the protective

portion (2a) of the needle body. As in the systems that have already been described, the needles are returned to the magazine after the lancing operation and the needle tip is retracted within the needle body (2a). The magazine is moved to the next position by moving the drive plunger of the lancing unit along direction (44) until the plunger can couple with a needle positioned in the adjacent chamber (42) in order to carry out a new lancing operation. If the lancet system has to be replaced in the lancing aid, the drive plunger must firstly be moved outside the rear area (46) of the needle body (2a). For this purpose the magazine is moved to the next position and at the same time the button (41) is pressed down by a ramp on the housing of the lancing aid. The button (41) is now shifted within the lancet system as shown in figures 4c and d so that the section (50) of the button protrudes from the bottom of the needle body (2a). In this position a recess (47) of the button (41) engages the rear area (48) of the needle (3) which prevents the lancing aid from coupling again with the lancet system as shown in the front view of figure 4d. Hence a lancing operation cannot be carried out with a lancet system of figure 4c or d. Moreover the lancet system cannot be reinserted into the lancing aid due to the change in the shape of the needle body in area (50). Hence the lancet system cannot be positioned via the guide groove (49) as part of a holding element.

Figure 5 shows a round-shaped lancet system which also contains several needles within the needle body. Similarly to figure 2, the lancet system has a multipart needle body. A channel (52) is arranged along the axis of rotation of the lancet system and a plug (53) is located in this channel at the upper end of the lancet system. The plug (53) is held in its first position by expanding holding arms (56) and this position represents the unused state of the lancet system. The holding arms (56) engage in a taper of the plug (53) which is formed by planes (55) of the plug which slant towards one another. When the lancet system is inserted into a lancing aid (70) the plug (53) is pressed within the channel (52) towards the needle tips by means of a centering plunger (57) of the lancing aid. The holding arms (56) are spread when the plunger is pressed in due to the slanting planes (55) of the plug (53). When the holding arms (56) of the lancet system are spread the plunger (57) can engage between them. Hence the plunger (57) can be almost completely inserted into the lancet system and is used as a bearing for and to position the magazine. An appropriately designed drive

unit of the lancing aid can thus be oriented relative to the lancets of the system such that it can be coupled to a lancet and a lancing operation can be carried out. After the magazine has been used it is removed from the lancing aid. For this purpose the plunger (57) is pulled out from the interior of the magazine housing while the plug (53) remains at the lower end of the magazine in the area of the needle tips. Consequently a used lancet system is designed as shown in figure 5c in which the plug (53) is no longer held in the upper section of the holding arms (56). If an attempt is made to insert the used lancet system into the lancing aid, the plunger (57) strikes the upper portion (56) of the holding arms which in their unspread state prevent the plunger from penetrating into the lancet system. The absence of the plug (53) prevents the plunger (57) of the lancing aid from spreading the holding arms and thus the lancet system cannot be placed in the lancing aid.

Figure 6 shows another embodiment of a lancet system that is arranged within a lancing aid. Figure 6a to d firstly show a lancet system that is similar to that of figure 1. Like figure 1 the system shown in figure 6 also has an elastomer (4) which surrounds the needle tip in a sterile manner and a two-part needle body which has a taper (5, 5') in its middle. The second part of the needle body (2b) whose movement is guided in the interior of the protective portion of the needle body (2a) also has arms (6) in its rear section which can couple in a form-fitting manner with a plunger (78) of the lancing aid (72). As shown in figure 6b and c, the plunger (78) engages with a head (71) in the second part (2b) of the needle body and moves the needle along the axis (8) in the direction of lancing. In this process the arms (6) of the needle body (2b) are pressed together and the projections (11) engage behind the notches in the head (71). The mode of operation of the lancet system is similar to that already described in figure 1 and is thus only shown again here with regard to its interaction with the lancing aid. The lancing aid (72) has a locking lever (74) that is mounted in the lancing aid and is rotatably pivoted on an axis (75). The locking lever (74) has a circular shape in a first area (77) such that the locking lever can engage in a form-fitting manner in the taper (5) of the lancet system.

Figure 6a shows the state of the lancing aid with the lancet system before use in the inserted state. If it is intended to use the lancing aid for a lancing operation, the

locking lever (74) is rotated by about 90° either automatically when a lancing operation is triggered or separately by the user, such that the lower section (77) of the locking lever no longer engages in the taper (5, 5'). The rotation of the locking lever is ensured by the fact that the lancing aid also has a depression (76) in the housing of the lancing aid which allows the locking lever to rotate around the axis of rotation (75). When the lancing operation is carried out, the second part of the needle body (2b) can move along the protective portion of the needle body (2a) and a section of the needle body (2b) emerges from the opening of the needle body (2a) without being hindered by the locking lever (74). In this process the needle tip is driven through the elastomer and the exit opening (9) of the lancet system and through an exit opening (73) of the lancing aid.

After the lancing operation the needle returns to its resting position during which, however, the second part of the needle body locks into the recess (13) of the protective portion of the needle body. As already described in figure 1, this results in a change in the outer shape of the needle body in the area of the taper (5) since the second part of the needle body (2b) now protrudes from the opening of the needle body (2a). After the lancet system has been removed from the lancing aid, the locking lever (74) rotates back into its initial position as shown in figure 6a. As indicated in figure 6d, a reinsertion of the lancet system into the lancing aid is blocked by the locking lever (74). The locking lever (74) can no longer engage in the taper (5) of the used lancet system since the taper (5) is partially closed by the second part of the needle body (2b). Hence the lancet system can no longer be positioned and thus held in its original position. The plunger (78) can no longer engage in the lancet system. The head (71) and the projections (11) are prevented from forming a form-fitting connection.

Figures 6e - h show embodiments similar to figures 6a – d in which the lancet system consists of a plurality of needles so that they can be stored in a magazine as shown in figure 2. The operating principles are, as already described, identical and can be simply transferred from the system with one needle to the system shown in figures 6e – h. At this point the intention is only to illustrate an embodiment that allows a magazine to be reinserted whose needles have only been partially used. For this the user must rotate

the magazine relative to the lancing aid housing until the locking lever (74) can engage in a taper (5) which is not blocked by a needle body (2b). This positioning of the lancet system relative to the lancing aid and consequently relative to the drive plunger ensures that only a lancet that has not yet been used is employed for the next lancing operation. An advance of the lancet system in only one direction of rotation and a mechanism that allows no more than one rotation of the lancet system by 360° can be added as required in order to prevent already used lancing aids from being used again.

Figure 7 shows another embodiment of a lancet system that is in the form of a round magazine housing. The needle body design has several parts similar to the figures that have already been described. The sterile protection and needles are also arranged as already described and thus a more detailed description is omitted here. Similar to the system described in figure 5 the blocking mechanism shown in figure 7 is also actuated when the lancet system is inserted into the lancing aid. For this purpose the needle body (2a) has a blocking mechanism (31) that is in the form of an outer ring that surrounds the upper section (35) of the needle body. When positioned at this position the blocking mechanism (31) essentially covers the elastic arms (90) that are located in the upper portion of the needle body (35). As a result the elastic arms (90) are pressed into the recess (95) of the needle body (2a). The blocking mechanism (31) also has a circular protrusion at its lower end that enlarges the circumference of the needle body (2a) at this position. If the lancet system is inserted into a lancing aid, the circumference of the lancing aid is selected such that the ring (96) cannot be inserted into the lancet system. The ring is pressed downwards relative to the needle body into the area of the lancet tips when the lancet system is inserted into the lancing aid by means of a lower edge (97) acting as a counter-flange for the lancing aid housing. As a result the spring-mounted locking arms (90) are released from the ring. The resting arms are now in a spread state in the lancing aid and are pressed against the inner housing wall (98) of the lancing aid. When a used lancet system is removed from the lancing aid, the locking arms (90) slide along the sloping housing wall (98) in a tapered area of the lancing aid housing and are firstly pressed into the recess (95) of the needle body due to the slanting wall (98). Hence the lancet system can be readily removed from the tapered area of the lancing aid. The used lancet system is subsequently present in a changed form as shown in figure 7c. When the

system is reinserted into a lancing aid the locking arms (90) are now spread and thus the circumference of the needle body (2a) is enlarged in the area (35) thus preventing an insertion of the lancet system into the front narrowed area of the lancing aid.

CLAIMS

1. Lancing aid for producing an opening in the skin comprising
   - a housing in which a lancet system can be at least partially inserted wherein
   - the housing also has a holding element that interacts with a corresponding holding element of the lancet system such that the lancet system is positioned in the housing at a defined position, and
   - the housing comprises an opening from which a needle tip of at least one needle can emerge from the lancet system during a lancing operation and
   - a drive mechanism for propelling the at least one needle such that the needle is transferred from a resting position into a lancing position and
   - the needle is connected to a needle body in such a manner that a protective portion of the needle body and the needle can be moved relative to one another and
   - the protective portion of the needle body at least partially surrounds the needle tip in a first position and
   - the protective portion of the needle body and the needle tip are arranged relative to one another in a second position in such a manner that the needle tip is released from the protective portion of the needle body and
   - the needle body also comprises a blocking mechanism that is actuated by an interaction with the lancing aid and changes the needle body in such a manner that, after ejection of the lancet system from the lancing aid, the holding element of the lancing aid is prevented from interacting with the holding element of the lancet system when it is reinserted again.

2. Lancing aid as claimed in claim 1,
   in which the holding element of the lancing aid is prevented from interacting with the holding element of the lancet system in such a manner that the lancet system cannot be reinserted into the lancing aid.

3. Lancing aid as claimed in claim 1,
   in which the lancet system and the lancing aid each have several, independently acting holding elements.

4. Lancing aid as claimed in claim 1, 2 or3,
in which the blocking mechanism prevents an interaction of the holding elements of the lancet system with the lancing aid in such a manner that the lancet system can be held and positioned in no position in the lancing aid.

5. Lancing aid as claimed in claim 1,
in which an interaction of the holding elements of the lancing aid and the lancet system is prevented in such a manner that the needle cannot be propelled by the drive mechanism.

6. Lancing aid as claimed in claim 1,
in which the blocking mechanism spatially separates the holding elements when the lancet system is reinserted into the lancing aid.

7. Lancing aid as claimed in claim 1,
in which the blocking mechanism is activated when the lancet system is ejected from the lancing aid.

8. Lancing aid as claimed in claim 1,
in which the blocking mechanism is activated when the lancet system is inserted into the lancing aid.

9. Lancing aid as claimed in claim 1,
in which the blocking mechanism is actuated during a lancing operation.

10. Lancing aid as claimed in claim 1,
in which the protective portion of the needle body is transferred to its first position during the ejection of the lancet system.

11. Lancing aid as claimed in claim 1,
in which the first position of the protective portion of the needle body is the same as the resting position.

12. Lancet system for insertion into a lancing aid comprising
- at least one needle with a tip for producing a skin opening and
- a needle body with a holding element that interacts with a holding element

of the lancing aid when the lancet system is inserted into a lancing aid in such a manner that the lancet system is positioned at a defined position in the lancing aid and

- the needle body is connected with the needle in such a manner that at least one protective portion of the needle body and the needle can be moved relative to one another,

wherein

- the protective portion of the needle body at least partially surrounds the needle tip in a first position and
- in a second position, the protective portion of the needle body and the needle tip are spatially separated from one another such that the needle tip is released by the protective portion of the needle body and
- the needle body also has a blocking mechanism that can be actuated by an interaction with a lancing aid and changes the needle body in such a manner that, after ejection of the lancet system from the lancing aid, the holding element is prevented from interacting with a holding element of a lancing aid when it is reinserted again.

13. Lancet system as claimed in claim 12,
in which the blocking mechanism changes the shape of the needle body.

14. Lancet system as claimed in claim 12,
in which the protective portion of the needle body is a magazine housing that contains a plurality of needles.

15. Lancet system as claimed in claim 12,
in which the needle body comprises several parts.

16. Lancet system as claimed in claim 12 or 15,
in which a part of the needle body comprises the blocking mechanism which is actuated independently of the protective portion of the needle body.

17. Lancet system as claimed in claim 12,
in which the blocking mechanism acts directly on the holding element and covers or destroys the holding element.

18. Lancet system as claimed in claim 12,
in which the shape of the needle body is itself designed as a holding element.

19. Lancet system as claimed in claim 12,
in which the blocking mechanism has a preset breaking point that breaks the needle body when it is ejected from the lancet system.

20. Lancet system as claimed in claim 12,
in which the blocking mechanism enlarges at least one area of the needle body.

21. Lancet system as claimed in claim 12,
in which the blocking mechanism reduces the size of at least one area of the needle body.