A DEVICE FOR PERFORMING AN INCISION

FIELD OF THE INVENTION

The present invention relates to a device for performing an incision for the collection of a blood sample, and more particularly, to a device for performing an incision on an individual's heel for diagnostic purposes.

BACKGROUND OF THE INVENTION

The heel stick procedure to puncture a newborn's heel to obtain a blood sample is widely practiced for babies aged 6 months and below. The blood samples obtained from this procedure are sent for diagnostic processing predominantly for screening of diseases, for example hypothyroidism, PKV (or phenylketonuria), galactosemia, sickle cell disease, HIV infection, etc. The advantages observed from the screening of these diseases are widely known and will not be discussed.

As the blood samples are to be obtained from infants, any incision should be made with minimum discomfort to the infant and therefore, issues like consistency in the type of incision or puncture, having a minimal depth of cut whilst still being able to obtain an adequate volume of blood for sampling to be performed, are critical. On the other hand, the device has to have ease of use and have repeatability of results.

For hygiene purposes, these devices are made for single usage and therefore, low cost of manufacturing is also a consideration so that a cheap and reliable device may be produced.

For the purposes of safety, the blades of the devices are usually stowed away to prevent cross contamination during disposal.

There are presently several lancet devices available in the market.

Some of these lancet devices produce an incision by way of a substantially downward thrust on a patient causing a puncture wound or a substantially vertical incision, others cause an incision profile by way of a slicing action causing a substantially lateral incision profile.

In the lancet devices of the prior art, the incision is activated by a trigger mechanism, which impacts a blade or blade-carrying portion to cause the incision to occur.

The problem with this type of activation is that the incision is activated indirectly. Possible problems caused by this indirect activation mechanism would be the possibility of the trigger mechanism being jammed or broken and the inconsistency of the impact force resulting in an inconsistent incision.

It is an object of the present invention to alleviate one or all of the above problems.

SUMMARY OF THE INVENTION

According to a first embodiment of the invention, there is provided a device for performing an incision in a region of interest of a patient, said device including a blade portion for providing the incision, said blade attached to a biasing means to enact a vertical force on said blade so that the blade is biased in a retracted position, a triggering means for activating the blade to move from a previously retained pre-operating position, to an operating position where the blade contacts a region of interest of the patient thereby performing an incision, a guide means to guide a path of the blade as it moves in an operating position said blade portion adapted to engage said guide means when in an operating position, so that a path of the blade in an operating

position is guided, the device further including a housing to house said device, said housing having an elongate slot at one end, where in an operating position, the blade extends therethrough said slot, and in a pre-operating position, the blade does not extend therethrough said slot, wherein the blade, biasing means and the triggering means are integral to one another, forming a plate.

Preferably, the guide means is a cam having accurate profile having a curved valley portion of a substantially central portion of the profile.

Still preferably, when the triggering means is depressed, the blade, biasing means and triggering means rotate about a point on the housing.

In a second embodiment, the device further includes a stopping means to maintain the blade in a post-operating position, where the blade does not contact the patient.

Preferably, the stopping means is an extended lip extending from a periphery of the housing, extended to project a portion of the triggering means so that the blade and the biasing means are retained in a post-operating system.

Still preferably, the stopping means further includes an extended finger, extending from the triggering means, to abut the extended lip so as to stop a rotation of the device.

In a third embodiment, the device further includes a retaining means to maintain the blade in a pre-operating position, where the blade does not contact the patient.

Preferably, the retaining means is a rotatable plate, rotatable about an edge of the housing to contact the triggering means so that it may not be depressed.

In a variation, the rotatable plate is a sheath.

In a fourth embodiment, the device further includes a cover adaptable to be fixed over at least the triggering means so that the triggering means will not be accidentally activated.

DESCRIPTION OF THE FIGURES

In order that the present invention might be more fully understood, embodiments of the invention will be described, by way of example only, with reference to the accompanying drawings, in which:

Figure 1 shows a first embodiment of the invention in a pre-operating position;

Figure 2 shows a profile of the incision using a guide means of the present invention;

Figure 3 shows a second embodiment of the invention having a stopping means in a post-operating position;

Figure 4 shows a third embodiment of the invention having a retaining means in the form of a safety catch in a pre-operating position;

Figure 5 shows the invention in an operating position;

Figure 6 shows a variation of the retaining means;

Figure 7 shows a fourth embodiment of the present invention;

Figure 8 shows a variation of the first embodiment of the present invention;

Figure 9 shows a variation of the second embodiment of the present invention in an operating position;

Figure 10 shows a variation of the second embodiment of the present invention in a post operating position;

Figure 11 shows a variation of the fourth embodiment of the present invention in a pre operating position; and

Figure 12 shows a variation of the fourth embodiment of the present invention in a post operating position.

In each of the aspects and variations, the same reference numerals have been used for similar components, merely for ease of understanding the specification.

DETAILED DESCRIPTION OF THE INVENTION

Reference will now be made in detail to the preferred embodiments of the invention, examples of which are illustrated in the accompanying drawings. While the invention will be described in conjunction with the preferred embodiments, it will be understood that they are not intended to limit the invention to these embodiments. On the contrary, the invention is intended to cover alternatives, modifications and equivalents, which may be included within the spirit and scope of the invention as defined by the appended claims. Furthermore, in the following detailed description of the present invention, numerous specific details are set forth in order to provide a thorough understanding of the present invention. However, it will be obvious to one of ordinary skill of the art that the present invention may be practiced without these specific details. In other instances, well known methods, procedures, components, and features have not been described in detail as not to unnecessarily obscure aspects of the present invention.

As shown in Figure 1, the present invention relates to a device 100 for performing an incision in a region of interest of a patient of a first embodiment. The device 100 is placed directly on, or proximal to a region of interest of a patient.

The device 100 includes a plate 10 wherein a triggering means 20, a blade holder 30 where a biasing means 40 resides. The biasing means 40 is in communication with the blade holder 30 and enacts an inward force on the blade holder 30, so that when a blade 39 is engaged with the blade holder 30, blade 39 is biased towards a retracted position. These 3 elements being integral to one another, the force relayed to the blade holder by the triggering means will be consistent and predictable, as the force affected on the triggering means will be translated to the blade holder and blade directly. The triggering means 20 activates the plate 10 to move from a pre-operating position, where the blade does not contact or cause an incision on a region of interest of a patient, to an operating position, where the blade contacts or causes an incision on a region of interest of a patient, and finally to a post-operating position. Figure 1 shows a first embodiment of the invention in a pre-operating position.

Essentially, as the triggering means 20 and blade holder 30 are provided in or otherwise integral to the plate 10, a force enacted on the triggering means 20 will consequently enact on the blade holder 30. A guide means 60 is also provided on the blade holder 30 to guide a path of the blade engaged in the blade holder when the device 100 is in an operating position so as to produce a consistent incision on a region of interest of a patient when the device is in an operating position.

In the embodiments, the surface profile of the guide means 60 has a cam having an arcuate profile with a curved valley portion at a substantially central portion of the profile, or in a skewed 'V' profile, however, it is envisioned that the guide means may be of any other profile to effect a desired incision profile on a patient.

The blade further includes an engagement means in the form of an aperture 34 complementary to an engagement protrusion 31 of the blade holder 30, , to engage the blade 39 to the blade holder 30. The blade has at least an aperture 34 dimensioned to engage with the engagement protrusion 31 of the blade holder 30. The guide means 60 is in the form of a guide protrusion on the blade holder 30 on an opposed side to the inward facing engagement protrusion 31. In Figure 1, the engagement protrusion and guide protrusion are integral as it extends inward to outward of the blade holder 30.

The guide protrusion is positioned at a pre-determined location along the blade holder 30 where it contacts the surface profile of the guide means 60. The pre-determined location of the guide protrusion is such that the biasing means 40 in communication with the blade holder and the blade, is held at a displacement from its equilibrium position so that the position of the blade is held in tension. The pre-determined location of the protrusion 31 and aperture 34 may be easily calculated by a person skilled in the art and will therefore not be discussed. When the triggering means 20 is activated or specifically, the triggering means is depressed, the plate is moved to an operating position by a substantially lateral force. By virtue of the biasing means, the guide protrusion 31 is in constant contact with a surface profile of the cam. Therefore when in an operating position, where a force is effected by the triggering means, the protrusion 31 traverses the surface profile of the cam. Consequently, the path of the blade follows the surface profile of the cam. Therefore, the surface profile of the cam determines the type, or rather, the profile of incision to be effected on a region of interest of a patient.

The device further includes a housing 70 wherein the plate 10 substantially resides. The plate 10 is pivotally connected about a point A to allow the plate 10 to rotate about a point. When in operating position, the plate 10 rotates about point A to move from a pre-operating position to a post-operating position when the triggering means 20 is activated.

During the period between the pre-operating and post-operating position, the plate 10 is in an operating position.

The housing 70 includes an elongated slot 71 wherein the blade 39 extends therethrough when in an operating position.

Therefore, the elongated slot 71 is the region along which an incision is made on a region of interest of a patient. As can be appreciated, when in use, the elongated slot is placed over the region of interest of a patient.

The position of the elongated slot 71 and the guide means is substantially in alignment with each other, so that the path of the blade, as it extends from the elongated slot 71, is guided and pre-determined. The profile of the incision using the guide means of a surface profile in the exemplary embodiment is shown in Figure 2. The incision is made by a lateral "slicing action" as opposed to a vertical "stabbing action". Advantageously, the incision action provided by the present device is better than a stab action because the resistance to the cutting edge of the blade being imposed on the skin and tissue is from small to big and then to small. This causes less pain than a stab action does. The width of the incision opening is parabolic, meaning it opens from a narrow to a wider, and ending with a narrow shape of wound. Wounds caused by this type of incision heals easily.

For the purposes of controlling blood volume after an incision, the best shape of incision would be a parabola. Specifically, as the object of the incision is a baby's heel, the depth of the incision should be controlled to a certain range. This is based on a combination of factors being the incision depth, incision opening length and the incision profile area.

Figure 3 shows a second embodiment of the present invention where the device 100 further includes a stopper means 80 to allow the rotation of the plate 10 to come to a stop at a post-operating position. At the post operating position, the blade would be retracted from the elongated slot 71 so that accidental incisions will not be made. The stopper means 80 maintains a post-operating position of the device and in this embodiment, the device 100 is a single-use device.

Figure 4 shows a third embodiment of the present invention where the device further includes a retaining means 90 so that the triggering means 20 will not be inadvertently triggered. The retaining means 90 retains the position of the triggering means 20 at a pre-operating position. The retaining means is shown as a rotatable plate 91, rotatable about an edge 75 of the housing to contact the triggering means so that it may not be depressed when the retaining means 90 is in place. When a user wishes to use the device, the rotatable plate 91 is rotated about the edge 75 so that the trigger may be depressed.

In the embodiments, the triggering means 20 and biasing means 40 are formed on the plate 10, the triggering means is in the form of a lever arm 21, which may be depressed downwardly to rotate the plate as a whole about the point of pivot A.

The point of pivot A is formed on an underside 72 of the housing in the form of a hole, the plate having a complementary protrusion is simply depressed into the hole to effect a connection. In this embodiment, the plate 10 is retained onto the protrusion by any known means in such a way that it may still rotate freely about the point of pivot A.

In a variation, the point of pivot A is formed on an underside 72 of the housing in the form of a protrusion, the plate having a complementary hole is simply depressed into the protrusion to effect a connection. In another embodiment, the plate 10 is retained onto the hole by any known means in such a way that it may still rotate freely about the point of pivot A.

The plate 10 has a recessed region 11 wherein the biasing means 40 resides. The biasing means 40 may be any known form of biasing means for example a spring, or any resilient material for example plastic.

The blade 39 may be engaged with the biasing means by any form of adhesion or it may be formed thereon the plate 10.

As seen in Figure 1, the extension of the finger 12 abuts the extended lip 73 when in a pre-operating position. By depressing the triggering means in the form of a lever arm 21, the force allows the lever arm 21 to overcome the extended lip 73 to rotate about the pivot A and be in an operating position. Advantageously, the force provided by depressing the lever arm 21 will cause the finger 12 to be initially stressed. This stress builds up until such time the extended lip 73 is overcome. Due to the resilience of the plate, the accumulated force will cause the plate 10 to rotate at a high speed. This causes the blade to move quickly and thereby reduce the pain of the patient during the incision.

The stopper means is in the form of a second finger 13 extending from the plate 10. The second finger 13 is dimensioned to be received in a recess 74 formed on an inner periphery of the housing when the device 100 is in a post-operating position. Additionally, at the post operating position, the finger 12 abuts the inner periphery of the housing 70.

Figures 1 and 4 show the device in a pre-operating position, Figure 3 shows the device in a post-operating position and Figure 5 shows the device in an operating position.

Figure 6 shows a variation of the third embodiment of the device. In this variation, the retaining means 90 is a sheath 92, which allows the triggering means or lever arm 21 to reside therein, when the device has been used. Maintaining the lever arm in the sheath also prevents the blade from moving from a post operating position to an operating position, and makes for easy disposal. The sheath 92 may be held in that position by any known means.

In a fourth embodiment as seen in Figure 7, the device has a cover 110 placed over the triggering means.

In a variation, the cover 110 is a cap and is affixed to at least two surfaces 111 to the housing of the device to prevent accidental activation of the triggering means. In this variation, the cover may be easily removed, or placed over the triggering means by a user.

In the embodiments, when in used, a user grasps the triggering means 20 preferably with a thumb, and the rest of fingers grasp an opposed end of the housing. To enhance the comfort of a user, the opposed end of the housing is provided with a ribbed or otherwise corrugated surface 76. Additionally, the ribs indicate a correct position where the fingers may rest so that a proper incision may be performed.

In further variations of the embodiments as seen in Figures 8 to 12, the shape of the triggering means is curved or otherwise ergonomically shaped to increase the comfort of a user using the device 100.

In these variations, the surface of the triggering means is ribbed or corrugated so that a firm grip may be effected.

In the variation of the first embodiment as shown in Figure 8, the device is shown in a pre-operating position. In the variation of the second embodiment, as seen in Figures 9 and 10. The device is shown in an operating position in Figure 9, and a post operating position in Figure 10.

Figures 11 and 12 show a variation of the fourth embodiment of the invention.

The embodiments of the invention have been advanced by way of example only, and modifications are possible within the scope of the invention as defined by the appended claims.

1. A cutting device for making an incision in a patient comprising:
    a. a housing;
    b. a support plate in the housing;
    c. a pivot element pivotally connecting the plate to the housing for pivotal movement from a retracted position to a cutting position;
    d. a trigger operatively connected to the plate for pivoting the plate;
    e. a blade mounted on said plate for linear movement from a retracted position to a cutting position;
    f. biasing means carried on the plate biasing the blade in a linear direction toward the retracted position;
    g. a cam; and
    h. connecting means operatively connecting the blade to the cam such that the cam extends the blade in a linear motion to the cutting position simultaneously with the pivoting movement of the plate to the cutting position.
2. The cutting device according to Claim 1 wherein the plate and the trigger comprise a one-piece element.
3. The cutting device of Claims 1 or 2 further including a stop element carried by the plate and engaging the housing for stopping the pivotal movement of the plate at a post cutting position.
4. The cutting device of Claims 1, 2 or 3 further including a retaining element projecting from the plate and engaging a portion of the housing such that, when the trigger is actuated, the force of the trigger overcomes the engagement with the housing portion whereby the plate pivots extremely rapidly through the cutting position to the post cutting position.
5. The device of Claim 4 wherein the relative size and shape of the retaining element and the housing portion is such as to prevent the retaining element from returning to the cutting position after reaching the post cutting position.

6. The cutting device of any of Claims 1 to 5 further including a movable retaining element in engagement with the trigger to prevent the plate from being pivoted out of the pre-cutting position.
7. The cutting device of Claim 6 wherein the movable retaining element comprises a pivotable element.
8. The cutting device of Claim 6 wherein the retaining element comprises a sheath.
9. The cutting device of Claim 6 wherein the retaining element comprises a removable cover over the trigger.
10. A medical cutting instrument comprising:
    a. a rotatable support element;
    b. a cutting blade carried by the rotatable support element;
    c. biasing means biasing the blade in a non-cutting direction;
    d. a finger-actuated lever operatively connected to the rotatable support element for manually moving the blade through an arcuate path from a pre-cutting position to a cutting position;
    e. retainer means preventing the plate and blade from movement until the force created by of the finger actuated lever is sufficient to overcome the retainer means; and
    f. actuator means arranged to overcome the biasing means and move the blade into a cutting position when the stop means are overcome and the blade is rotated through an arcuate cutting path by the rotatable support element.