

LANCET DEVICE

Technical Field of Invention

- 5 The invention relates generally to medical puncturing devices used in taking blood samples from patients. The devices are commonly known as lancets. More specifically, the invention relates to lancets which are activated by contact with the patient's skin or tissue, during normal use.

Description of Related Art

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Lancets are commonly used both in medical facilities and by private individuals. The devices are used to obtain a blood sample from a patient by puncturing the skin or tissue of the patient. The blood then swells to the surface and can then be used on a sample card. This is used when only a small amount of blood is required as opposed to an amount to be taken by hypodermic syringe.

- 15 Diseases, such as diabetes, require blood testing at regular intervals to monitor blood sugar levels of the patient. Further, test kits often require a blood sample for analysis. Obtaining a sample of blood usually involves pricking a finger or other suitable body part. Usually, a small amount of blood is needed for such tests which can be obtained by a small puncture of the skin.

- 20 In view of blood-borne diseases, it is important that, after use of the device, other persons do not come into contact with the lancet needle. Thus, an important aspect of a lancet device involves preventing the needle from wounding another person after the skin of the patient has been punctured. The needle should be shielded, after use of the device, to prevent accidental wounding of another person. Further, the lancet device should be disposable to reduce the
- 25 possibility of disease transmission due to the device being used on other persons. In this respect, the lancet device should preferably be a single use device with features to prevent reuse.

- US 5,540,709 discloses a lancet device which is activated upon contact by finger (or other body part) to be pierced. The device contains, in an armed position, a lance with its needle and a
- 30 spring affixed to the lance and a trigger. The trigger includes a mechanism to release the lance during use. Depression of the trigger against the body part releases the lance and the spring so that the needle protrudes through an orifice in the end of the trigger and pierces the tissue. The spring is held in a pre-armed position, release of the spring is consistent, and reproducibility of incision is well controlled.

US 6,432,120 B1 discloses a contact activated lancet device. The device has a lancet holder and a trigger (triggering device) enclosing a lancet structure. The trigger interacts with the lancet holder via a triggering element to maintain the spring in a compressed state such that the lancet structure is in a stable standby position which is not easily triggered by accidental bumps on the assembly. The device is assembled with the spring in the compressed state.

Lancet devices of US 5,540,709 and US 6,432,120 B1 are pre-armed prior to use on a patient. With pre-armed lancet devices there is a potential of triggering prior to application on a patient's skin rendering the device not usable.

WO 2006/110571 A2 discloses a push activated lancet device. The device comprising a lancet having a puncturing element disposed within a two-piece housing including a rear housing and a forward housing. Relative axial movement of the rear housing toward the forward housing directly drives the lancet to a puncturing position wherein the puncturing element extends through the forward housing. During such relative axial movement, a drive structure applies a driving force against the lancet and disengages from the lancet based on deflecting structure in the housing, thereby releasing the driving force applied to the lancet. A retention member then retracts the lancet back within the housing, with the drive structure maintained disengaged from the lancet to prevent re-use.

To activate the lancet device of WO 2006/110571 A2, the user must initially provide a threshold of pressure to overcome a frictional interference engagement between the rear housing and the forward housing. The driving momentum forcing the lancet to the puncturing position is provided directly through the force of the user.

WO 2005/110227 A1 discloses a contact activated lancet device including a lancet structure with a puncturing element within a housing structure. The device includes a drive spring and a pivotal lever in interference engagement with the lancet structure. An actuator within the housing pivots the lever, to move the lancet structure toward the rearward end of the housing to at least partially compress the drive spring and thereby releasing the lever from interference engagement with the lancet structure allowing the lancet structure to propel forward.

Lancet device of WO 2005/110227 has a complicated arrangement for retaining and releasing the lancet structure and is difficult to manufacture and assemble.

WO 2003/092512 discloses a contact activated lancet device having a cocking seat and a lancet with a piercing tip moveably disposed within the open interior, and a biasing assembly engaging the lancet. The cocking seat is structured to engage the lancet and move the lancet against a force of the biasing assembly. A release element is provided to disengage the lancet from the cocking seat such that the piercing tip of the lancet is driven at least temporarily into a piercing orientation.

In the lancet device of WO 2003/092512, the lancet is disengaged from an interfering engagement during axial movement of the lancet.

In this specification where reference has been made to patent specifications, other external documents, or other sources of information, this is generally for the purpose of providing a context for discussing the features of the invention. Unless specifically stated otherwise, reference to such external documents is not to be construed as an admission that such documents, or such sources of information, in any jurisdiction, are prior art, or form part of the common general knowledge in the art.

It is an object of the present invention to provide a medical puncturing device, known as a “lancet” which overcomes or at least partly overcomes some of the abovementioned disadvantages or at least will provide the public with a useful choice.

Summary of invention

In a first aspect the present invention may be said to broadly consist in a **safety lancet (10)**, comprising or including,

a. a hollow housing (11), with a longitudinal axis (118) and a proximal end (18) and distal end (20), said hollow housing (11) including,

a proximal end opening (72) extending through the hollow housing (11) to a housing interior (24), and

at least one guide rail (94 or 96) on an interior wall (22) of said housing interior, extending in a direction between said proximal end and distal end, said guide rail including a free end (100), and

b. a driver (14) retained by said hollow housing (11) in sliding engagement with said hollow housing (11), said driver comprising,

a trigger portion (66 and 68) to protrude at least in part from said proximal end,
at least one drive portion (80, 82, 84, 86) extending into said housing interior,

5 that includes a driving surface (90),

c. a lancet holder (52) that carries a lance (54), said lancet holder in sliding and rotational engagement within said housing interior, said lancet holder defining a drivable surface (64) that can engage the driving surface of the driver, the lance carried by said lancet holder in an orientation with a puncturing end (58) of said lance directed toward said proximal end, and

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d. a biasing means (12 or 46) to urge said lancet holder toward said proximal end and against said driver,

wherein at least one of the driving and drivable surfaces is angled to bias the lancet holder against the guide rail during displacement of the lancet holder towards the distal end and to send the drivable surface over the free end once the drivable surface is driven towards the distal end until the drivable surface is able to rotate about the longitudinal axis and then pass over said free end and be fired by the biasing means with sufficient momentum toward the proximal end to extend the lancet puncturing end through the proximal end opening with sufficient force to pierce tissue (116) brought into contact therewith and then be retracted by said biasing means sufficient to hold said puncturing end not beyond said proximal end opening.

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Preferably said driving surface is planar and extends perpendicular to said longitudinal axis, with a surface normal of the driving surface being at an angle to the longitudinal axis and extending toward said distal end.

Preferably said drivable surface is a following surface to at least in part be able to slide on said driving surface.

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Alternatively said drivable surface is planar and extends perpendicular to said longitudinal axis, with a surface normal of the drivable surface at an angle to the longitudinal axis and extending toward said proximal end.

Preferably said drivable surface is a following surface to at least in part be able to slide on said driving surface.

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Preferably said driving surface is complimentary (and preferably prior to firing, contiguous) to said drivable surface.

Preferably said free end is located at a distal edge of the guide rail and is preferably an end surface of said guide rail ("guide rail end surface").

Preferably the orthogonal of any guide rail end surface normal is perpendicular to said longitudinal axis.

Preferably said guide rail end surface is planar.

5 Preferably said guide rail end surface is planar and wherein said drivable surface is planar and extends perpendicular to said longitudinal axis, with a surface normal of the drivable surface at an angle to the longitudinal axis and extending toward said proximal end, said guide rail end surface and said drivable surface being parallel to each other.

Preferably said drive portion comprises at least one elongate leg that defines said driving surface at the distal end thereof.

10 Preferably said leg is in sliding engagement with a longitudinally extending guide surface of said guide rail.

Preferably said leg is in said sliding engagement with said guide surface.

Preferably said trigger portion, at least before firing, extends through said proximal end opening.

15 Preferably said trigger portion includes an aperture there through, define an opening for said lancet puncturing end to pass through during firing.

Preferably said guide rail is parallel to said longitudinal axis.

Preferably said guide rail is non parallel to the longitudinal axis.

Preferably there are a plurality of guide rails equi-spaced on said interior wall.

20 Preferably said plurality of guide rails forms a plurality of channels therebetween.

Preferably there are corresponding drivable surfaces and corresponding number of driving portions that each lie in alternate said channels and wherein the drivable surfaces, after firing, become located in the other of said channels.

25 Preferably each said driving portion is guided by at least one guide surface of one of said plurality of guide rails either side of said channel.

Preferably there is a one to one matching of drivable surfaces to said driving surfaces.

Preferably said drivable surface or surfaces are on a proximal end oriented surface or surfaces of an arm or arms radially arranged on said lancet holder.

30 Preferably said arm or arms lie in every other of said channels when said drivable surface has passed over said free edge.

Preferably said lance is covered by a removable guard that is removable from the lance prior to displacement of the lancet holder.

Preferably said safety lancet is a single use lancet.

Preferably there are stops at said proximal end to retain said driver and said lancet holder

within said hollow housing (11).

Preferably said angle to said longitudinal axis of said normal is within a range of 10^0 to 80^0 (and preferably is at 45^0 to said longitudinal axis).

5 Preferably said angle to said longitudinal axis of said normal is within a range of 10^0 to 80^0 (and preferably is at 45^0 to said longitudinal axis).

Preferably the lancet holder has a bore to stably retain the lancet.

Preferably said lance is co-axial with said longitudinal axis.

Preferably the lancet is either a needle or a blade.

10 Preferably there is an engagement member integrally formed with the lancet holder to engage the biasing means.

Preferably there is a base cover for closing the hollow housing at the distal end.

Preferably a guide member is provided to enable location of the lancet holder and driver within the housing as an assembly, in the correct relative rotational orientation between the lancet holder and the driver and between the assembly and the housing.

15 Preferably any aperture toward a distal end of said base cover is closed by a base cap.

Preferably said proximal end opening, on an inward facing surface thereof, contains at least one groove for a complimentary part of said driver to move in, said at least one groove closed at its distal end to limit axial movement of the driver via said complimentary part therein.

Preferably said plurality of guide rails consists of an alternating long rails and short rails.

20 Preferably said short rail has said guide rail end surface.

Preferably said elongate leg has a stop surface to engage said stops.

Preferably said stop surface is formed by a proximal presenting surface on said elongate leg.

Preferably the biasing means is a spring.

25 Preferably a safety cover is present for covering the proximal end to prevent accidental actuation of the device.

Preferably the safety cover comprises a cap connected to a ring by frangible links.

Preferably removal of the safety cover also removes the removable guard from the lance.

Preferably the removable guard is attachable to the safety cover by a clip of the removal guard that can clip into an aperture of the safety cover.

30 Preferably a cap cover engages with said safety cap to at least in part cover the aperture of the safety cover and at least in part retain the extension to the safety cap.

Preferably said hollow housing is circular in cross-section.

Preferably said safety lancet is supplied in a first or loaded condition where it is ready to be fired.

In a further aspect the present invention consists in a **safety lancet** as herein described with reference to any one or more of the accompanying drawings.

According to an embodiment of the invention is a lancet device comprising a lancet
5 element configured for axial and rotational movement, a biasing assembly coupled to the lancet
element for driving the lancet element from a disengagement position to a puncture position and
an actuating element engaged to the lancet element for axially and rotationally moving the lancet
element against the biasing assembly to disengagement therewith, at the disengagement position
wherein rotation of the lancet element relative to the actuating element effects disengagement
10 between the actuating element and lancet element.

Preferably the lancet element and the actuating element are in frictional engagement.

Preferably the lancet element comprises a cam surface which frictionally engages a corresponding
15 cam surface on the actuating element.

Preferably the cam surfaces are inclined for rotation of lancet element.

Preferably the cam surfaces are inclined to 45° .
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Preferably rotation of lancet element occurs when the frictional engagement between the lancet
element and the actuating element is overcome.

Preferably the lancet element comprises a lancet having a puncture tip and a holder having a bore
25 to stably retain the lancet.

Preferably the lancet is either a needle or a blade.

Preferably the holder comprises at least one arm for engaging the actuating element.
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Preferably the lancet element comprises at least one arm having the cam surface.

Preferably the lancet element further comprises an engagement member for coupling to the
biasing assembly.

Preferably the engagement member is an alignment boss.

Preferably the actuating element comprises a disc having a puncture hole and at least one prop.

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Preferably the actuating element comprises at least one prop having the cam surface.

Preferably the lancet device further comprises a housing having a proximal end and a distal end and an internal cavity, wherein the lancet element, actuating element and biasing assembly are contained within the internal cavity.

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Preferably the lancet device further comprises a base cover for sealing the internal cavity at the distal end.

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Preferably the lancet device further comprises a rim for partially sealing the internal cavity at the proximal end.

Preferably the lancet device further comprises a collar for receiving the actuating member to expose a surface of the actuating member therefrom to exterior of the housing.

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Preferably the collar comprises closed grooves for limiting axial movement of the actuating element.

Preferably the actuating element further comprises arms for slidable engagement within the grooves.

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Preferably the housing has an interior wall comprising guide rails extending from the rim to the base cover for engaging the at least one prop and the at least one arm.

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Preferably the guide rails consist of alternating long rails and short rails.

Preferably passageways alternate with the guide rails.

Preferably the at least one prop is retained within one of the passageways.

Preferably one of the short rail engages the at least one arm after disengagement of lancet element to guide the at least one arm into one of the passageway.

- 5 Preferably the interior wall further comprises ridges within each passageway for abutting the at least one prop and the at least one arm.

Preferably the biasing assembly is a biasing means.

- 10 Preferably the biasing assembly further comprises a coupling member.

Preferably the coupling member is an alignment boss.

- 15 Preferably the biasing assembly retracts the lancet element from the puncture position due to an overextension of the biasing assembly.

Preferably the housing has finger grips indentations.

- 20 Preferably the lancet device further comprises a safety cover for covering the proximal end to prevent accidental actuation of the device.

Preferably the safety cover comprises a cap connected to a ring by frangible links.

- 25 This invention may also be said broadly to consist in the parts, elements and features referred to or indicated in the specification of the application, individually or collectively, and any or all combinations of any two or more of said parts, elements and features, and where specific integers are mentioned herein which have known equivalents in the art to which this invention relates, such known equivalents are deemed to be incorporated herein as if individually set forth.

- 30 Brief Description of Drawings

A device in accordance with the invention will now be described by way of example with reference to the accompanying drawings in which:

Figure 1 is a side view of an assembled lancet device in accordance with the present invention;

Figure 2 is an exploded view of lancet device of Fig 1;

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Figure 3 is an exploded isometric view of lancet device of Fig 1;

Figure 4 is a cross-section side view of a pre-actuated lancet device;

10 Figure 5 is a cross-section side view of an actuated (first condition) lancet device with the lancet holder as a structure for holding the lancet in a puncture position;

Figure 6 is a cross-section side view of an actuated lancet device with the lancet holder retracted within the housing after executing a puncture;

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Figure 7 is a schematic side view of a pre-actuated lancet device;

Figure 8 is a schematic side view of an actuated lancet device with the lancet holder in a puncture position; and

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Figure 9 is a schematic side view of an actuated lancet device with the lancet holder retracted within the housing after executing a puncture;

Figure 10 shows a zoomed in internal detail of the interface of the lancet holder and the driver with the device housing, showing the series of arms of activation, firing and retrieval of the lancet, where,

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Figure 10 (a) shows the arrangement prior to activation of the driver by pressing the device against the patient's tissue,

Figure 10, (b) shows the movement of the driver and lancet holder towards the housing distal end relative to the short rail and against the biasing means, e.g. a spring,

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Figure 10(c) shows alignment of the contact surface of the lancet holder with the end wall of the short rail, and the start of the sliding of the arm of the lancet down this inclined composite surface, due to the combination of the inclined surface and the biasing means or spring,

Figure 10(d) shows the arm having slide off the inclined composite surface and moving down

into the gap next to the short rail,

Figure 10(e) shows the lancet exiting the housing of the device to puncture the patient's skin or tissue, due to the movement imparted to it by the biasing means, and

Figure 10(f) shows the lancet being retracted into the device as the biasing means over comes its
5 movement caused over extension, to leave the lancet within the housing,

Figure 11 shows a variation of the interaction of Figure 10 of the driving surface of the driver and the drivable surface of the lancet holder, rather than 2 complimentary planar surfaces, there

is shown in Figure 11a a planar drivable surface of the lancet holder that slides on a drivable

surface as a following surface (e.g. a smooth round surface) of the driver, whereas in Figure 11b

10 it is reversed to have the driving surface as the planar driving surface and the drivable surface is a following surface,

Figure 12 shows an exploded view of a second embodiment of the present invention,

Figure 13 shows the hollow housing of the second embodiment at:

- (a) front view,
- 15 (b) vertical section view,
- (c) bottom view, and
- (d) isometric view,

Figure 14 shows the lancet holder at:

- (a) front view,
- 20 (b) right hand side view,
- (c) back view with hidden detail showing the lancet,
- (d) plan view, and
- (e) isometric view,

Figure 15 shows the guide body in:

- 25 (a) front view,
- (b) vertical sectional view along line B-B,
- (c) bottom view, and
- (d) isometric view,
- (e) bottom isometric view, and
- 30 (f) top isometric view,

Figure 16 shows the driver in:

- (a) a front view,
- (b) a side view,
- (c) bottom view, and

(d) isometric view,

Figure 17 shows the cap cover in bottom isometric view,

Figure 18 shows the cap at:

(a) invertical sectional view, and

5 (b) isometric view,

Figure 19 shows the base cap of the second embodiment in top isometric view, and

Figure 20 shows the spring of the second embodiment in:

(a) plan view, and

(b) front view.

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Detailed Description of the Invention

With reference to the above drawings, a safety lancet device 10 according to an embodiment of the invention is shown. Safety lancet 10 generally includes a hollow housing 11, a biasing assembly 12 and a lancet assembly 13 movably associated with the hollow housing 11. The lancet
15 assembly 13 includes a driver 14 and a lancet holder 16. The hollow housing 11 has a proximal end 18, which is the end placed on the skin or tissue 116 of a patient to be punctured, and a distal end 20, which is the end opposite to the proximal end 18. The proximal end 18 of the hollow housing has a proximal end opening 127.

20 Driver 14 is in part disposed within the hollow housing 11 and a patient contact portion or abutment surface extends partially from the hollow housing 11 at the proximal end 18 via the proximal end opening 127.

Lancet assembly 13 is axially or longitudinally movable within the hollow housing 11. Lancet
25 holder 16 is operatively associated with driver 14. It is to be understood that such axial movement includes any movement of the driver 14 and the lancet holder 16 relative to each other, including axial and/ or rotational movement of either element or both elements with respect to the general length of hollow housing 11.

30 Hollow housing 11 may be formed integrally. Alternatively hollow housing 11 may be formed in separate parts, divided lengthwise or otherwise. Each part may be affixed to each other through an appropriate adhesive or through appropriate inter-engaging structures which provide a mechanical attachment between the parts, such as frictional fit or snap fit construction.

The hollow housing 11 includes an elongated body 21, both having a common central longitudinal axis. It is to be understood that body 21 may be formed in any suitable form. Preferably body 21 is cylindrical. The interior of body 21 is generally hollow. Body 21 has an interior wall 22 of an annular cross-section. Interior wall 22 defines a uniform cylindrical internal cavity 24 which extends from the proximal end 18 to the distal end 20. Driver 14 and lancet holder 16 are contained within internal cavity 24. Body 21 may have plurality of external ribs 25 extending longitudinally from the distal end 20 to the proximal end 18 of hollow housing 11. Ribs 25 aid the patient in gripping safety lancet device 10. Other configurations can be used to provide a surface which improves the grip of safety lancet 10. For example outer surface of body 22 may be configured to accommodate a patient's finger, such as finger grip indentations or may be textured or otherwise.

In the preferred embodiment housing 11 includes a rim 26 extending from body 21 and inward of the central longitudinal axis of body 21, outer edge of rim 26 being joined to body 21. Preferably rim 26 is perpendicular to body 21. Rim 26 partially seals internal cavity 24 at the proximal end 18 of hollow housing 11. The inner edge of rim 26 encircles an annular aperture 28. Aperture 28 communicates with internal cavity 24. Hollow housing 11 may include a collar 30 which projects from rim 26 parallel to the central longitudinal axis of body 21 stretching around the inner edge of rim 26 and thereby encircling a vestibule 32. One end of vestibule 32 is aperture 28. Vestibule 32 and aperture 28 have equivalent diameters. Opposite to aperture 28 is an opening 33 of vestibule 32. Vestibule 32 communicates with internal cavity 24 through aperture 28.

Rim 26 and collar 30 may be integrally formed with body 21. Alternatively, rim 26 and collar 30 may be formed as a unitary component separate from and then affixed to body 21. In such a configuration rim 26 with collar 30 is affixed to proximal end 18 of body 21 through an appropriate adhesive or through an appropriate inter-engaging structure, such as frictional fit, snap fit construction or threaded construction, which provide a mechanical attachment between rim 26 and body 21 at proximal end 18. Driver 14 partially extends from the hollow housing 11, out of opening 33, through aperture 28 and vestibule 32.

At distal end 20 of hollow housing 11 is a rear opening 34 leading to internal cavity 24. A base cover 36 engages body 21 at rear opening 34 to close the internal cavity 24 such that the central longitudinal axis of body 22 intersects the centre point of base cover 36. Base cover 36 is not

necessary where a two part construction of hollow housing 11, divided lengthwise, is optionally adopted.

Base cover 36 may be formed as a separate element from body 21. Base cover 36 may be affixed to body 21 at the distal end 20 by an appropriate adhesive or an inter-engaging structure which provides a mechanical attachment therebetween, such as frictional fit, snap fit construction, or threaded engagement or otherwise. Base cover 36 includes a plate 38. Preferably plate 38 has a border corresponding to body 21. For a snap-fit configuration for an inter-engaging structure between base cover 36 and body 21, clasps 40 are mounted to one side of plate 38. Clasps 40 have mating surfaces 42 for coupling to corresponding recesses 44 on interior wall 22 of body 21. Clasps 40 are positioned adjacent the border of plate 38 at either sides of the central point of base cover 34. Body 21 may optionally be provided with guides, on interior wall 22, leading to recesses 44. When base cover 36 is engaged to body 22, clasps 40 extend along interior wall 22 with mating surfaces 42 snap fitting into recesses 44. Clasps 40 are preferably composed of resilient material. It is to be understood that arrangement of the foregoing components of the inter-engaging structure between base cover 36 and body 21 are merely exemplary and it is contemplated that other inter-engaging structures may be used to fit body 21 with base cover 36.

The biasing assembly 12 abuts against the base cover 36 when assembled. Lancet assembly 13 is engaged to biasing assembly 12 for movement of the lancet assembly 13 in the hollow housing 11 and for operative interaction between driver 14 and lancet holder 16 of the lancet assembly. Biasing assembly 12 is configured to exert a biasing force against lancet holder 16 such that lancet holder 16 is driven toward the proximal end. The biasing assembly 12 may be a separate element coupled to plate 38 of base cover 36 or may be integrally formed with plate 38.

Biasing assembly 12 may be a biasing means 46, for example a resilient member such as but not limited to a coil spring, coupled to plate 38 or integrally formed with plate 38. Preferably the biasing means 46 is a metal or plastic spring. Alternatively, biasing assembly 12 may additionally include a coupling member 48 connected to plate 38 of base over 36 to couple biasing means 46 to plate 38. Coupling member 48 is positioned at the centre of plate 38 such that when then base cover 36 engages body 21 at rear opening 38 to close the internal cavity 24, the central longitudinal axis of body 21 intersects coupling member 48. Coupling member 48 supports biasing means 46 in a proper orientation for engagement with lancet assembly 13. Preferably the coupling member 48 is an alignment boss for accommodating one end of the biasing means 46.

Lancet assembly 13 may include an engagement member 50 for engagement with the opposite end of the biasing means 46. Preferably, the engagement member 50 is an alignment boss for accommodating the opposite end of the biasing means 46. In a preferred embodiment, biasing means 46 is coupled between coupling member 48 connected to base cover 36 and engagement member 50 connected to lancet assembly 13. During initial stages of actuation of safety lancet 10, lancet assembly 13 is pushed axially into hollow housing against biasing assembly 12, causing biasing assembly 12 to store energy, e.g. by compression. Upon release of the compression force, the potential energy stored in the biasing assembly 12 exerts a force against the lancet holder 16 of lancet assembly 12 for biasing the lancet holder 16 along the central longitudinal axis of hollow housing 11 towards proximal end 18 to reach the puncture point through vestibule 32. Lancet holder 16 reaches the puncture point temporarily. Due to the momentum of the biasing assembly 12 and lancet assembly an over extension of the biasing assembly 12 is caused. The biasing assembly 12 then contracts inwards from its over extended condition and the lancet holder 16 is retracted into the hollow housing 11. Retraction of the lancet holder 16 eliminates the possibility of transmission of blood borne diseases through accidental wounding after use of the lancet.

The lancet assembly 13 includes the driver 14 and the lancet holder 16 which are configured for movement along the central longitudinal axis of hollow housing 11 and subsequent firing of the lancet holder 16 for puncturing of the patient's skin or tissue 116.

Lancet holder 16 has a longitudinal rotational axis and includes a stem 52 which may be formed as a rod. One end of the stem 52 may be connected to the engagement member 50 and both may be formed a single unit. The opposite end of stem 52 is configured to receive a lancet 54. A bore 56 is present partially extending through stem 52, from the end receiving the lancet 54. The bore is co-axial with the longitudinal axis 118 of the hollow housing. Bore 56 may be shaped in accordance with the lancet 54 which is to be used in safety lancet 10.

The lance 54 may be captured within the lancet holder 52 by moulding of the lancet holder, or part thereof, onto the lance 54. Alternatively it may be located therein with an interference fit or may have a complimentary structure engagement.

Bore 56 stably retains the lancet 54 in lancet holder 16. When lancet 54 is inserted into bore 56,

the lancet 54 is aligned along the rotational axis of lancet holder 16. Preferably, extending from stem 52 parallel with the rotational axis of lancet holder 16 is a sleeve 53. Sleeve 53 extends along the opening of bore 56 at the inner periphery of stem 52. Sleeve 53 provides additional support to lancet 54.

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Lancet 54 may be a needle or a blade having a puncture end 58. The puncture end 58 is adapted for puncturing the skin of a patient at a puncture point and may define a pointed end or a blade edge and may also include a preferred alignment orientation.

- 10 Lancet holder 16 is adapted for longitudinal and rotational movement within hollow housing 11 and is sequentially movable from an initial position with the puncture end 58 within the proximal end 18 of hollow housing 11, to an disengagement position where biasing assembly 11 is compressed and lancet holder disengages from driver 14, to a puncturing position in which the puncturing end 58 is biased to extend through vestibule 32 beyond opening 33 (to puncture
- 15 patient's skin or tissue) and finally to a post-puncture position with the puncture end 58 being withdrawn into hollow housing 11.

- The lancet holder 16 includes arms 60 attached to stem 52. Each arm 60 extending radially and preferably perpendicular away from the longitudinal axis of lancet holder 16. Preferably stem 52
- 20 and arms 60 are integrally formed. Each arm 60 is spaced at regular intervals around stem 52 to form gaps 62. It is to be understood that the number of arms 60 may be varied without departing from the spirit of the invention so long at least one gap 62 is provided. For example in some embodiments only one arm 60 may be present.

- 25 In an assembled safety lancet 10, arms 60 extend from the point of attachment to stem 52 to interior wall 22 and are configured to slidably contact interior wall 22, during longitudinal and rotational movement of lancet holder 16, within hollow housing 11. Preferably, surfaces of arms 60 which contact interior wall 22 are formed with a corresponding curvature to that of interior wall 22. Length of arms 60 are preferably equal and are such that when lancet holder 16 is
- 30 positioned in hollow housing 11, stem 52 is centrally located within hollow housing 11 and between interior wall 22 and the rotational axis of lancet holder 16 is aligned to the central longitudinal axis of hollow housing 11.

Each arm 60 includes a drivable surface. In the preferred embodiment the drivable surface is an

engagement surface 64 through which the lancet holder 16 interacts with driver 14. Each engagement surface 64 has an inner edge attached to stem 52 and an outer edge in movable contact with interior wall 22. Each engagement surface 64 generally faces the proximal end 18 of hollow housing 11. The engagement surface 64 lies on a radial line from the longitudinal axis, in other words it is perpendicular to the longitudinal axis 118. The engagement surface is also rotated about this radial line, so that a normal of the engagement surface is inclined at an angle to the longitudinal axis.

The engagement surface 64 is between a 10^0 to 80^0 angle of inclination and in the preferred embodiments has a 45^0 angle of inclination. The degree of inclination may be varied as will be described hereinafter. The engagement surfaces 64 of each arm 60 are inclined in the same direction and have the same degree of inclination. It is to be understood that arms 60 are formed to provide a platform for engagement with driver 14 during unitary movement therewith and are therefore formed to withstand forces applied to the lancet holder.

Driver 14 has a longitudinal axis and includes a disc 66 which defines a puncture surface 68 for contacting the patient's skin to be punctured by the lancet 54. Disc 66 includes an abutment surface 70 opposite the puncture surface 68. Centre point of disc 66 is aligned with the longitudinal axis of driver 14. Disc 66 is movable through vestibule 32 of hollow housing 11. Disc 66 may have a bevelled outer edge which reduces frictional contact between outer edge of disc 66 and wall of collar 30 which encloses vestibule 32. Towards the centre of disc 66 is an inner edge which defines a puncture hole 72. Hole 72 extends through disc 66 in the direction of the longitudinal axis of driver 14. When safety lancet 10 is placed against the patient's skin, puncture surface 68 of disc 66 contacts the patient's skin. As safety lancet 10 is actuated, part of the patient's skin distends into puncture hole 72. After safety lancet 10 is actuated, puncture end 58 of lancet 54 is fired through puncture hole 72 to puncture the patient's skin.

Longitudinal movement of driver 14 may be limited and rotational movement is preferably restricted as will now be described. Vestibule 32 may include grooves 74 at opposed sides. Each groove 74 being parallel to the central longitudinal axis of hollow housing 11 and extends from the opening 33 of vestibule 32 towards aperture 28. Grooves 74 are separated from the aperture 28 by lips 76. Lips 76 may also be positioned at opening 33 of the vestibule 32. Clip arms 78 may be attached to disc 66 at abutment surface 70. When driver 14 is positioned in hollow housing 11, in an assembled device, disc 66 is slidably enclosed by vestibule 32 with clip arms 78

correspondingly located in and slidably associated with respective grooves 74. Range of longitudinal movement of disc 66, and therefore driver 14, is limited by movement of clip arms 78 along grooves 78, and by lips 72. Disc 66 is restricted from any rotational movement by inter-engagement of clip arms 78 with walls of grooves 74.

5

Extending from abutment surface 70 are driving portions such as radial props 80. Preferably disc 66 and props 80 are integrally formed. Each prop 80 includes a leg 82 extending parallel to the longitudinal axis of driver 14. At the end of each leg 82 is a radially outward flange 84 extending generally perpendicularly from leg 80 away from the longitudinal axis of driver 14. Length of flange 84 may be equivalent to the breadth of rim 26 between interior wall 22 and edge of aperture 28. A foot 86 extends from each flange 84 generally parallel to leg 82. Outer surface of foot 86 is configured to contact and slide along interior wall 22 during longitudinal movement of driver 14 within hollow housing 11. Preferably, outer surface of each foot 86 which contacts interior wall 22 is formed with a corresponding curvature to that of interior wall 22. The driving portion therefore consists of props 80, legs 82, flanges 84, and feet 86.

10

At the end of each foot 86 is an inclined driving surface as contact surface 90. In the preferred embodiment the inclination of contact surfaces 90 corresponds and is complimentary to the inclination of engagement surfaces 64 of arms 60.

20

In other forms of the invention the driving surface and drivable surface need only be able to slide relative to each other. Many ways to achieve this will be evident to a person skilled in the art. One such way is that shown in Figure 11. Figure 11a shows the arm 60 having an inclined drivable surface as a planar drivable surface 124, which engages a driving surface as a following surface 123, in this case as an extension of the foot 86 of the driving portion. As the driving portion rises up under actuation of the lancet the planar drivable surface 124 of the arm 60 will be able to slide or follow over the following surface 123 when clear of the free end 120 of the end wall 100.

25

An equivalent opposite structure is shown in Figure 11b wherein the driving surface is a planar driving surface 122 as part of foot 86 on which the drivable surface as following surface 123 can slide.

30

In other embodiments the driving surfaces and/or the drivable surfaces and/or the end walls

may be curved or otherwise formed provided the drivable surface can slide or pass over the driving surface and the end wall or free end.

The outer edge of arms 60 and outer surface of feet 86 form an even surface. Preferably, flanges
5 84 are formed parallel to contact surfaces 90 and therefore having the same degree of inclination.

Props 80 are spaced at regular intervals around the outer periphery of disc 66 to form slots 88.
Driver 14 and lancet holder 16 are moveable towards each other after disengagement by way of
arms 60 of lancet holder 16 being moveable into slots 88 of driver 14 and props 80 of driver 14
10 being moveable into gaps 62 of lancet holder 16. It is to be understood that the number of props
80 should be the same as the number of arms 60.

When safety lancet 10 is assembled, central longitudinal axis of hollow housing 11, axis of driver
14 and rotational axis of lancet holder 16 coincide. Prior to actuation of safety lancet 10, driver
15 14 is positioned in hollow housing 11 with engagement surfaces 64 and contact surfaces 90 in
frictional engagement. It is to be understood that the degree of inclination may be suitably varied
in order to retain engagement surfaces 64 and contact surfaces 90 in frictional engagement till
overcome by opposing forces, one acting on driver 14 and the other acting on lancet holder 16.

20 Upon contact of puncture surface 68 with a patient's skin or tissue 116, driver 14 is pushed
axially into hollow housing 11 toward the distal end 20. As driver 14 and lancet holder 16 are in
abutting engagement, both move as a single unit against biasing assembly 12. This results in
compression of biasing assembly 12 which results in an increase in the potential energy of biasing
assembly 12. As biasing assembly 12 is compressed, the biasing assembly 12 exerts a force
25 against the lancet assembly 13. Opposing forces thus act on lancet assembly 13 along the
longitudinal axis of hollow housing 11.

As described at least one of the driving or drivable surfaces is angled to bias the lancet holder 52
or a surface there of against the guide rail 96 or guide surface 125 thereof during displacement of
30 the lancet holder towards the distal end 20. When sufficiently displaced toward the distal end 20
the drivable surface of the lancet holder is sent over the free end 120 of the short guide rail 94,
due to its being free of rotational constraint of the guide rail 96 or its guide surface 125. The
lancet holder is then able to rotate about the longitudinal axis 118 and then pass over the free
end 120. It is then fired by the biasing means with sufficient momentum toward the proximal

end 18 to extend the lancet puncturing end 58 through the proximal end opening 72 with sufficient force to pierce tissue 116 brought into contact therewith. Then the lancet holder 52 is retracted by the biasing means sufficient to hold the puncturing end 58 not beyond the proximal end opening 72.

5

Initially, frictional force between engagement surfaces 64 and contact surfaces 90 is greater than the combined forces from the biasing assembly 12 and from the pushing force from the patient allowing lancet holder 16 and driver 14 to move as a single unit. As the safety lancet 10 is pressured against the patient lancet assembly 13 is pushed further into hollow housing 11 thereby increasing the potential energy of biasing assembly 12 and increasing the combined forces on lancet assembly 13. The combined forces increase till the frictional force between engagement surfaces 64 and contact surfaces 90 is overcome causing engagement surfaces 64 and contact surfaces 90 to slide against each other due to their off axis alignment. Sliding of the surfaces against each other is achieved due to lancet holder 16 being able rotate around its rotational axis.

15 But as described herein, driver 14 is unable to undergo any rotational movement.

Continued increase in the combined forces results in further sliding between engagement surfaces 64 and contact surfaces 90 till the surfaces disengage.

20 However continued relative rotational movement is prevented by arms 60 grooves

In the assembled safety lancet 10, contact surfaces 90 of driver 14 have edges which are nearer the distal end 20 and edges which are nearer the distal end 20. Disengagement occurs at the edges nearer the proximal end 18. Each side of feet 86 adjacent the edge nearer the proximal end 18 at which disengagement occurs is hereinafter known as “disengagement side” 92.

25

Once disengagement occurs, potential energy in the biasing assembly 12 is released to fire the lancet holder 16 axially along the central longitudinal axis of hollow housing 11 toward proximal end 18. Lancet holder 16 moves towards disc 66 and puncture end 58 of lancet 54 slides through puncture hole 72 to reach the puncture point on the patient's skin thereby puncturing the skin. Further movement of lancet holder 16 is restricted by stem 52 abutting against abutment surface 70 of disc 66. Biasing assembly 12 then pulls back lancet holder 16 into hollow housing 11, to shield puncture end 58 within hollow housing 11.

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In a preferred embodiment, interior wall 22 may have a set of guide rails 94, 96 for engaging the feet 86 of driver 14 and for guiding the arms 60 of lancet holder 16. Long rails 94 alternate with short rails 96. The number of long rails 94 and number of short rails 96 correspond to the number of props 80 and arms 60. The guide rails extend from rim 26 towards distal end 20, parallel to the central longitudinal axis of housing 11. Between, long rails 94 and short rails 96 are channels or passageways 98. The elongate sides of the guide rails 94, 96 define guide surfaces 125 that guide the elongate portions of the drive portions, i.e. props 80, legs, 82, flanges 84 and feet 86. These guide surfaces also guide the arms 60 until they reach the free end 120 of the end wall 100 of the short rail 96.

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In the assembled safety lancet 10, feet 86 of driver 14 are held in passageways 98 and guided by guide surfaces 125 to further restrict rotational movement but allow axial movement of driver 14 within hollow housing 12. The number of passageways 98 equals the combined number of feet 86 and arms 60. Hence, in a pre-actuated safety lancet 10 there are passageways 98 which remain unoccupied as arms 60 are engaged with feet 86. Preferably, long rails 94 extend beyond the point along hollow housing 11 at which disengagement occurs between lancet holder 16 and driver 14. Preferably, short rails 96 extend till the position of contact surfaces 90 on hollow housing 11, when the driver 14 is in a pre-actuated position.

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Short rails 96 have end walls 100 which are inclined in the same direction as contact surfaces 90 and correspond to engagement surfaces 64. Short rails 96 are positioned on disengagement side 92 of feet 86. After actuation of safety lancet 10, at the moment of disengagement between driver 14 and lancet holder 16, contact surfaces 90 are either in line with or slightly proud of end walls 100. Hence, arms 60 slide over feet 86 at the disengagement side 92 and slide along end walls 100 by combination of biasing assembly 12 and the angled surfaces. As end walls 100 are correspondingly inclined, engagement surfaces 64 of arms 60 slide along end walls 100 into unoccupied passageways 98.

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Passageways 98 may include ridges 102 extending from rim 26 partway into the passageways 98.

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Ridges 102 provide abutment surface for flanges 84 of driver 14 and arms 60 of lancet holder 16. Longitudinal movement of driver 14 towards proximal end 18 is restricted by abutment of flange 84 and ridge 102. After actuation movement of lancet holder 16 towards proximal end 18 is restricted by abutment of arm 60 and ridge 102. Preferably, ridges 102 are inclined correspondingly to engagement surfaces 64 of arm 60.

In a preferred embodiment safety lancet 10 may include a cover 104 to protectively cover the puncture surface 68 at distal end 18 of driver 14 prior to actuation of the safety lancet 10. Cover 104 maintains sterility prior to use prevents accidental firing of safety lancet 10 and acts as a tamper evident structure. Cover 104 includes a cap 106 linked to a ring 108 through frangible links 110. Ring 108 encircles cap 106 and is anchored to the outer periphery of rim 26 through hooks 112. Outer periphery of rim 26 has notches 114 which correspond to hooks 110. To remove cap 106, the patient grips the cap 106 and performs a rotary screw or axial pulling motion thereby breaking the links 110 between cap 106 and ring 108. Once links 110 are broken the cap 106 cannot be replaced. Hence, removal of cap 104 provides a visual identification that the device 10 has been used or tampered with. Optionally, the cover 104 may be excluded. In such an embodiment lancet 54 is formed with a breakable component which encases the puncture end 58.

The respective elements of device 10 are typically formed of molded plastic material, such as medical grade plastic material. The lancet 54 may be constructed of any suitable material adapted for puncturing the skin and is typically surgical grade metal such as stainless steel.

In a preferred embodiment of assembled safety lancet 10, lancet assembly 13 and biasing assembly 12 are contained within the internal cavity 24 of hollow housing 11. The internal cavity 24 is sealed or and closed at the distal end 20 by base cover 36. Lancet assembly is positioned such that disc 66 of driver 14 partially extends at proximal end 18 from hollow housing 11, through opening 33, thereby exposing puncture surface 68. A cover 104 is provided at proximal end 18 over puncture surface 68. Biasing assembly 12 is coupled between the base cover 36 and lancet assembly 13. Biasing assembly 12 is compressed by a small degree for imparting a force on lancet assembly 13 to hold the lancet assembly 13 in place through abutment of flanges 84 of driver 14 against ridges 102 on interior wall 22 of hollow housing 11. Force imparted by biasing assembly 12 is of sufficient value to maintain, in a pre-actuated safety lancet 10, exposure of puncture surface 68 beyond opening 33 of vestibule 32 and to maintain driver 14 and lancet holder 16 in engagement. Short rails 96 keep lancet holder 16 from rotating and being driven towards proximal end 18 and to the puncture point.

To actuate safety lancet 10, a patient or a medical personnel grips body 21 of hollow housing 11 and the cap 106. The cap is first detached by performing a rotary screw or axial pulling motion

of the cap 106. The cap 106 is then discarded. Proximal end 18 of hollow housing 11 is then placed onto the patient's skin at a puncture point from which a sample of blood is to be obtained. Specifically the puncture surface 68 of driver 14 contacts the patient's skin. Generally, safety lancet 10 should be held perpendicular to the skin.

5

Still gripping body 21, the user (e.g. the patient or medical professional) begins pushing safety lancet 10 against the patient's skin or tissue 116 resulting in lancet assembly 13 being driven axially into hollow housing 11, along the longitudinal axis, towards proximal end 20. The patient or the medical personnel may place a finger or thumb on base cover 36 at distal end 20 to impart a greater pushing force to safety lancet 10.

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As lancet assembly 13 is driven further into hollow housing 11 against biasing assembly 12, biasing assembly 12 is further compressed. The biasing assembly 12 imparts an opposite force onto the lancet assembly 13. Rotational movement of driver 14 is limited by abutment of arms 78 on disc 66 with lips 76 on the wall enclosing vestibule 32 as well as sliding engagement of props 89 legs 82 and feet 86 against rails- preferably the short rails 96.

15

Opposed forces from the biasing assembly 12 and driver 14, which receives the pushing force from the patient's skin, act on lancet holder 16. Compression of biasing assembly 12 also increases the potential energy stored therein. The combination of the opposed forces increase until the disengagement side 92 of the arm 60 engagement surface 64 due to axial motion towards the distal end 20 comes level with or proud to the disengagement side 92 of the short rail 96 angled end wall. The surface is then free to slide down end wall 100 as the lancet holder rotates resulting in disengagement of lancet holder 16 from driver 14.

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Upon disengagement, potential energy in the biasing assembly drives lancet holder 16, towards proximal end 18. Lancet holder 16 is guided by temporary engagement of arms 60 with end walls 100 of short rails 96 into unoccupied passageways 98. Lancet holder 16 continues towards proximal end 18 till arms 60 abut ridges 102 in passageways 98 and stem 52 abuts abutment surface 70. At this point, puncture end 58 of lancet 54 temporarily enters puncture hole 72 of driver 14 at proximal end 18 to puncture the patient's skin at the puncture point.

25

The lancet holder 16 then retracts into hollow housing 11 towards distal end 20 by biasing assembly 12 which was in an overextended position due to momentum of lancet assembly 13

and biasing assembly 12 when puncture end 58 was at the puncture point. Biasing assembly 12 was overextended due to the release of potential energy which carried the biasing assembly 12 to a point of over extension. Retraction of lancet holder 16 by biasing assembly 12 pulls puncture end 58 of lancet 54 into hollow housing 11 thereby shielding puncture end 58, which may carry blood or other material from the patient, from puncturing skin of another individual. It is to be understood that after actuation of safety lancet 10 it is no longer possible to return driver 14 and lancet holder 16 to their pre-actuation positions without disassembly of the safety lancet 10. This provides an additional safety feature as safety lancet 10 can only be used once and should be discarded after use. It should be noted that actuation of safety lancet 10 is achieved through sequential arming and release of the lancet holder 16 by way of a single continuous motion.

A further embodiment of the present invention will now be described with reference to Figures 12-20. Where like integers are present in the second embodiment they refer to the same or similar features as in the first embodiment.

The second embodiment has differences in some of the components of the safety lancet and has some additional components, but otherwise functions in an identical fashion to the first embodiment.

The second embodiment has a cap 106 that attaches indirectly to the hollow housing 11. There is also a cap cover 132 that covers an aperture in the cap 106. A guide body 144 is used for assembly of the driver 14 and the lancet holder 16 to the hollow housing 11. There is also a base cap 131 to cover any aperture in the hollow housing 11 distal end. The lancet holder 16 in the second embodiment has only two arms 60 as opposed to four in the first embodiment. The arms 60 still have a drivable surface 64 as shown, and the firing functionality of the lancet holder 16, driver 14 and housing 11 is identical to that of the first embodiment.

Detailed features of the differences in the second embodiment will now be described.

Toward the proximal end 18 of the lancet holder 16 there is a removable guard 130. The removable guard 130 and the lancet holder 16 completely cover the lance 54. The removable guard 130 has towards its distal end 18 removable guard clips 134 whose function will shortly be described.

The assembly of the lancet holder, lancet and removable cover can be derived in a number of ways. However in the preferred embodiment the lancet holder body and the removable guard 130 are moulded over the lance 54. The lancet holder 16 and removable guard 130 can be moulded as one or separate pieces over the lance 54. A frangible region 135 as a thin connecting
5 portion between the body of the lancet holder 52 and the removable guard 130 allows breaking of the removable guard 130 from the body of the lancet holder 16 for its removal. In other embodiments where the removable guard is moulded separate to the lancet body the retention of the removable guard to the lancet is by interference fit between the removable guard and the lancet. Once the removable guard 130 is removed then the puncturing end 58 of the lance 54 is
10 exposed.

The removable guard functions as a protector for the lance 54 both from a damage and hygiene perspective. The removal of the removable guard 130 at the last possible moment prior to use of the device ensures that the lance is kept hygienic and not damaged. It also protects against
15 damage during assembly and handling of the individual components.

The cap 106 has a base cap aperture 137 through the upper or distal part of its construction. This allows the removable guard clip 134 (as indicated in dotted line in Figure 18a) to engage with the cap 106, once the lancet holder 16 and the driver 14 are assembled in the housing 11. A
20 cap cover 132 engages into the space between the removable guard clip 134 to retain them in an outwards position to engage on the base cap aperture 137; the legs of the cap cover 132 passing into the gap between the removable guard clips 134. The removable guard 130 may engage in other ways to the cap 106. Therefore the removable guard 130 is retained to the cap 106 and the assembly of the cap 106, removable guard 130 and cap cover 132 is removable as a sub-
25 assembly.

There is also present a removable guide body 144 to help with assembly of the safety lancet. The guide body, when engaged with the distal end 20 opening of the hollow housing, allows the assembly of the driver 14 and the lancet holder 16 in the correct pre-firing orientation with the
30 hollow housing 11.

The guide body 144 has a guide aperture 140 through its middle. The guide aperture 140 is complimentary to the axial cross-sections of the driver 14 and the lancet holder 16. Therefore the driver 14 and lancet holder 16 can only be moved through the guide aperture 140 in one

rotational orientation.

The guide body 144 also has a locating portion that consists of at least one elongate guide leg 138. In the preferred embodiment there are two such elongate guide legs 138. In addition the locating portion consists of a locating feature 142 that engages in a complimentary feature 150 in the hollow housing 11 when the guide body 144 is inserted into the hollow housing 11. The locating feature 142 will only engage its complimentary feature 150 when the guide body 144 is in the correct rotational orientation about the longitudinal axis.

The elongate guide legs 138 are sufficiently long such that they extend into the hollow housing and abut against the free ends 120 of the short rails 96. If the guide body is in the incorrect orientation, such as the elongate guide legs butting against the free ends of the long rails 94 then the operator / assembly machine can detect this as the guide body will not be inserted all the way home in the hollow housing 11.

Each elongate guide leg 138 has a guide surface 152 that extends along its length from the guide aperture 140.

The guide aperture 140 and guide surface(s) 152 (and 152a) therefore define a guide for the side surfaces of the drive portions 86 of the driver 14, and the arms 60 of the lancet holder 16. The guide body 144 is located in the correct orientation on the distal end of the hollow housing 11, the driver 14 and then the lancet holder are passed through the guide aperture (proximal ends first) and pass down into the hollow housing, guided by the guide surface 152 to be located in the channel defined by the short guide rail 96, that is on the pre-firing side 154 of the free end 100 of the short rail 96.

In the preferred embodiment there is a second guide surface 152a extending along the length of a secondary elongate guide leg 138a. This secondary guide surface 152a also extends from the guide aperture 140. The guide surfaces 152 in co-operation with their secondary guide surfaces 152a define a channel from the guide aperture 140 down to the pre-firing side 154 of the short rail 96. In this way the driver 14 and lancet holder 16 cannot go anywhere but into the correct location if the guide body is correctly engaged with the hollow housing 11.

In this way the guide body 144 aides in the assembly of the lancet device and reduces the

possibility of incorrect assembly. Once the driver 14 and lancet holder 16 are located in the correct pre-firing rotational orientation the guide body 144 can be removed and assembly can continue.

- 5 Once assembled in this manner the upper part of the removable guard 130 extends through and presents from the proximal portion proximal end 18 of the driver 14 and hollow housing 11. The cap 106 can then be located over the removable guard clips 134 and secured thereto. Thereafter the cap cover 132 can also be located into place to lock that sub-assembly together. If there is any aperture in the end of the housing 11 distal end of the cover 36 then a base cap
10 131 engages into the bottom of the base cover 36. In this way the resulting lancet assembly is better sealed against contaminants and damage.

- In using the second embodiment the cap 106 is twisted or pulled and this removes the cap cover 132 and removable guard 130. This exposes the trigger portion of the driver 14 and the lancet is
15 then ready to use.

- The driver 14 has a longer stroke to fire the lancet. To achieve this, the driver has more axial length of trigger portion exposed than the first embodiment. This ensures that it is a positive action that fires the device and not a slight or minor touch to the trigger portion of driver 14.
20

- The hollow housing 11 can also have different external finishing. This is to allow different look and feel to the product. The simplest way of achieving this is to have a changeable cavity side of the moulding that forms the hollow housing 11, for example when the hollow housing is made from injection moulding of a plastic. In this way simple changing of the cavity side with
25 different textures shape or features can allow the finished hollow housing 11 to have different external features.

- Where in the foregoing description reference has been made to elements or integers having known equivalents, then such equivalents are included as if they were individually set forth.
30

Although the invention has been described by way of example and with reference to particular embodiments, it is to be understood that modifications and/or improvements may be made without departing from the scope or spirit of the invention.

Claims

1. A **safety lancet (10)**, comprising or including,

a. a hollow housing (11), with a longitudinal axis (118) and a proximal end (18) and distal end (20), said hollow housing (11) including,

5 a proximal end opening (72) extending through the hollow housing (11) to a housing interior (24), and

at least one guide rail (94 or 96) on an interior wall (22) of said housing interior (24), extending in a direction between said proximal end (18) and distal end (20), said guide rail (94, 96) including a free end (100), and

10 b. a driver (14) slidable with respect to the hollow housing (11) and comprising,

a trigger portion (66 and 68) which protrudes at least in part from said proximal end (18),

at least one drive portion (80, 82, 84, 86) positioned in the housing interior (24), and including a driving surface (90),

15 c. a lancet holder (16) that carries a lance (54), said lancet holder (16) being slidable and rotatable with respect to the housing interior (24), said lancet holder (16) defining a drivable surface (64) that is able to engage the driving surface (90) of the driver (14), the lance (54) carried by said lancet holder (16) in an orientation with a puncturing end (58) of said lance directed toward said proximal end (18), and

20 d. a biasing means (46) positioned between the lancet holder (16) and the distal end (20), adapted to bias the lancet holder toward said proximal end (18) and against said driver (14),

wherein at least one of said driving (90) and drivable (64) surfaces is angled to bias the lancet holder (16) against the guide rail (96) during displacement of the lancet holder (16) towards the distal end (20) and to send the drivable surface (64) over the free end (100) once the drivable surface (64) is driven towards the distal end (20) until the drivable surface (64) is able to rotate about the longitudinal axis (118) and then pass over said free end (100) and be fired by the biasing means (46) with sufficient momentum toward the proximal end (18) to extend the lancet puncturing end (58) through the proximal end opening (72) with sufficient force to pierce tissue (116) brought into contact therewith and then be retracted by said biasing means (46) sufficient to hold said puncturing end (58) not beyond said proximal end opening (72).

2. A safety lancet as claimed in claim 1 wherein said driving surface is planar and extends perpendicular to said longitudinal axis, with a surface normal of the driving surface being at an angle to the longitudinal axis and extending toward said distal end.

3. A safety lancet as claimed in claim 2 wherein said drivable surface is a following surface to

at least in part be able to slide on said driving surface.

4. A safety lancet as claimed in claim 1 wherein said drivable surface is planar and extends perpendicular to said longitudinal axis, with a surface normal of the drivable surface at an angle to the longitudinal axis and extending toward said proximal end (18).
- 5 5. A safety lancet as claimed in claim 4 wherein said drivable surface is a following surface to at least in part slide on said driving surface.
6. A safety lancet as claimed in claim 1 wherein said driving surface is complimentary (and preferably prior to firing, contiguous) to said drivable surface.
7. A safety lancet as claimed in claim 1 wherein said free end is located at a distal edge of the
- 10 guide rail and is preferably an end surface of said at least one guide rail ("guide rail end surface").
8. A safety lancet as claimed in claim 7 wherein the orthogonal of any guide rail end surface normal is perpendicular to said longitudinal axis.
9. A safety lancet as claimed in claim 7 wherein said guide rail end surface is planar.
10. A safety lancet as claimed in claim 7 wherein said drivable surface is planar and extends
- 15 perpendicular to said longitudinal axis, with a surface normal of the drivable surface at an angle to the longitudinal axis and extending toward said proximal end (18), said guide rail end surface and said drivable surface being parallel to each other.
11. A safety lancet as claimed in claim 1 wherein said drive portion comprises at least one elongate leg that defines said driving surface at the distal end thereof.
- 20 12. A safety lancet as claimed in claim 11 wherein said elongate leg is in sliding engagement with a longitudinally extending guide surface of said guide rail.
13. A safety lancet as claimed in claim 1 wherein said trigger portion, at least before firing, extends through said proximal end opening.
14. A safety lancet as claimed in claim 1 wherein said trigger portion includes an aperture there
- 25 through, to define an opening for said lancet puncturing end to pass through during firing.
15. A safety lancet as claimed in claim 1 wherein said guide rail is parallel to said longitudinal axis.
16. A safety lancet as claimed in claim 1 wherein said guide rail is non parallel to the longitudinal axis.
- 30 17. A safety lancet as claimed in claim 1 wherein there are a plurality of guide rails equi-spaced on said interior wall.
18. A safety lancet as claimed in claim 17 wherein said plurality of guide rails form a plurality of channels therebetween.
19. A safety lancet as claimed in claim 18 wherein there are corresponding drivable surfaces

and corresponding number of driving portions that each lie in alternate said channels and wherein the drivable surfaces, after firing, become located in the other of said channels.

20. A safety lancet as claimed in claim 19 wherein each said driving portion is guided by at least one guide surface of one of said plurality of guide rails either side of said channel.
- 5 21. A safety lancet as claimed in claim 1 wherein each said driving surface has a corresponding drivable surface.
22. A safety lancet as claimed in claim 1 wherein each said drivable surface is on a proximal end oriented surface or surfaces of an arm radially arranged on or about said lancet holder.
23. A safety lancet as claimed in claim 1 wherein said lance is covered by a removable guard
- 10 that is removable from the lance prior to displacement of the lancet holder.
24. A safety lancet as claimed in claim 1 wherein said safety lancet is a single use lancet.
25. A safety lancet as claimed in claim 11 wherein there are stops at said proximal end to retain said driver and said lancet holder within said hollow housing.
26. A safety lancet according to claim 2 wherein said angle to said longitudinal axis of said
- 15 normal is within a range of 10^0 to 80^0 (and preferably is at 45^0 to said longitudinal axis).
27. A safety lancet according to claim 4 wherein said angle to said longitudinal axis of said normal is within a range of 10^0 to 80^0 (and preferably is at 45^0 to said longitudinal axis).
28. A safety lancet as claimed in claim 1 wherein said lancet holder has a bore to stably retain said lancet.
- 20 29. A safety lancet as claimed in claim 1 wherein said lance is co-axial with said longitudinal axis.
30. A safety lancet as claimed in claim 1 wherein said lancet is a either a needle or a blade.
31. A safety lancet as claimed in claim 1 wherein there is an engagement member integrally formed with the lancet holder to engage said biasing means.
- 25 32. A safety lancet as claimed in claim 1 wherein a guide body is provided to locate with the distal end opening of said hollow housing to enable assembly in the correct pre-firing rotational orientation of the driver and lancet holder within said hollow housing, said guide body being removable after assembly of said driver and lancet holder with said hollow housing.
33. A safety lancet as claimed in claim 32 wherein a guide aperture is provided in said guide
- 30 body complimentary to the axial cross sectional shape of said driver and said lancet holder and opening into said hollow housing when assembled therewith, and wherein said guide body comprises,
 - at least one locating portion to engage with said hollow housing,
 - wherein said at least one locating portion aligns said guide aperture on said hollow

housing to allow assembly therethrough of said driver and said lancet holder into the correct pre-firing orientation against said guide rail of said hollow housing.

34. A safety lancet as claimed in claim 33 wherein said at least one locating portion includes an elongate guide leg to extend into said hollow housing to lie against or toward said free end, said
5 elongate guide leg including a guide surface, for said driver and lancet holder, running from said guide aperture towards said free end, said guide surface aligned with said guide rail to deliver said driver and said lancet holder to said guide rail during assembly.
35. A safety lancet as claimed in claim 1 wherein there is a base cover for closing an opening of the hollow housing at the distal end.
- 10 36. A safety lancet as claimed in claim 1 wherein said proximal end opening, on an inward facing surface thereof, contains at least one groove for a complimentary part of said driver to move in, said at least one groove closed at its distal end to limit axial movement of the driver via said complimentary part therein.
37. A safety lancet as claimed in claim 17 wherein said plurality of guide rails consists of an
15 alternating long rails and short rails.
38. A safety lancet as claimed in claim 37 wherein said short rail has said guide rail end surface.
39. A safety lancet as claimed in claim 25 wherein said elongate leg has a stop surface to engage said stops.
40. A safety lancet as claimed in claim 39 wherein said stop surface is formed by a proximal
20 presenting surface on said elongate leg.
41. A safety lancet as claimed in claim 1 wherein said biasing means is a spring.
42. A safety lancet as claimed in claim 23 further comprising a safety cover for covering the otherwise open proximal end and trigger portion to prevent accidental actuation of said device.
43. A safety lancet according to claim 42 wherein said safety cover comprises a cap connected
25 to a ring by frangible links.
44. A safety lancet according to claim 43 wherein removal of said safety cover also removes said removable guard from said lance.
45. A safety lancet according to claim 44 wherein said removable guard is attachable to said safety cover by a clip of said removal guard that can clip into an aperture of said safety cover.
- 30 46. A safety lancet according to claim 45 wherein a cap cover engages with said safety cap to at least in part cover said aperture of said safety cover and at least in part retain said removable guard to said safety cap.
47. A safety lancet as claimed in claim 1 wherein said hollow housing (11) is circular in cross-section.

48. A safety lancet as claimed in claim 1 wherein said safety lancet is supplied in a first or loaded condition where it is ready to be fired.