Ref. Only

LANCET ASSEMBLY

FIELD OF THE INVENTION

The present invention is related to finger-pricking devices. In particular, the present invention is related to lancets for medical use.

BACKGROUND OF THE INVENTION

Lancets or finger-pricking devices is widely used in the medical field for applications such as skin incisions and blood drawing. In some lancet assemblies, the blade or needle is kept in a standby position until it is triggered by the user, who is typically a medical personnel in charge of drawing the blood from a patient. In other lancet assemblies, the user has to manually set the assembly to an armed position before firing can be triggered. Upon triggering, the blade fires onto the skin of the patient, for example on the finger, and makes an incision.

Such lancet assemblies must be sterilized before use, and the lancet maintained under sterile conditions until use. Furthermore, the lancet assembly should be disposable to eliminate the chances of disease transmission due to the blade being used on more than one person. In this regard, the lancet should ideally be designed for only one firing, and have safety features to prevent reuse. Other features which are

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desirable include safety features to reduce the chance of the lancet accidentally misfiring and pricking someone.

It is therefore an object of the present invention to provide a safe and reliable lancet assembly.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a perspective view of the triggler in Fig. 1 with the side walls cut away to expose the internal features.

Figure 2 is the bottom view of the triggler according to the present invention.

Figure 3A is an exploded perspective view of the lancet assembly according to the present invention.

Figure 3B is an exploded cross-sectional view of the lancet assembly along line A-A according to the present invention.

Figures 4A and B are longitudinal cross-sectional views along line A-A of the lancet assembly in the after use and firing positions respectively according to the present invention.

Figures 4C and D are longitudinal cross-sectional views along line A-A of the lancet assembly in the standby position with (Fig.4C) or without (Fig.4D) the protective cap according to the present invention.

SUMMARY OF THE INVENTION

Accordingly, the present invention provides in one aspect a lancet assembly having a distal end, a proximal end and a longitudinal axis running therebetween. The triggler is partially inserted into a lancet holder from the distal end. The lancet holder is provided with a rigid internal spring holder to receive a spring-loaded lancet structure. The lancet structure is provided with a body coupled to a spring which extend from the proximal end of the body. A lancet is attached to the body with the sharp tip pointing towards the distal end. The triggler interacts with the lancet holder via a triggering means 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 standby position is automatically maintained, and an additional arming step is eliminated. In another aspect, the assembly is provided with a safety feature to prevent tampering of the lancet assembly. In yet another aspect, the spring is secured to the end wall of lancet holder such that dislocation caused by the sudden expansion force of the firing process is prevented. Furthermore, the spring is chosen to over-extend upon firing, such that the sharp tip of the lancet can jab a patient's skin held outside the lancet holder upon firing, but the sharp tip is withdrawn safely back into the lancet assembly when the spring is recoiled into the resting position.

In the preferred embodiment, the lancet holder is provided with an open distal end and a closed proximal end defined by an end wall. Side walls extend from the end walls to form a box-like exterior casing. A mating means, preferably disposed on the interior surface of the side walls, is provided to interact with the triggler. The lancet holder also contains an elongated spring holder having an open first end and a second end attached to and extending from the end wall of the lancet holder. The supporting structures between the first end and the second end defines an interior space wherein the lancet structure is received. A receiving means is provided on the spring holder for mating with a guiding element on the lancet structure such that the lancet can move along the longitudinal axis. A securing element is provided near the proximal end of the lancet holder for securing the proximal end of the spring from dislocation during firing.

The triggler contains an end wall for closing the open distal end of the lancet holder. This triggler end wall contains an aperture wherethrough the sharp tip of the lancet fires when triggered. A stabilizing element, extending from the triggler end wall, is inserted between the side walls of the lancet holder and the supporting structures of the spring holder, allowing sliding movement of the triggler relative to the lancet holder along the longitudinal axis. This sliding movement is limited by a safety catch on the triggler which is designed to engage the mating means of the lancet holder such that

the triggler is maintained between a standby position and a firing position. A triggering means is also provided in the triggler for engagement with the guiding element of the lancet structure. When the triggler and the triggering means are in the standby position, the guiding element is forced towards the proximal end of the lancet holder, such that the spring is maintained in the standby position of a compressed high potential energy state. When a compression force is applied to the triggler end wall in the direction of the proximal end, the triggering means may be moved into a firing position in which it is disengaged from the guiding element. Once the guiding element is no longer held in the standby position, the potential energy stored in the compressed spring is released and the spring extends, forcing the sharp tip of the lancet structure to fire through the aperture of the triggler end wall.

DESCRIPTION OF THE INVENTION

The lancet assembly according to the present invention has a longitudinal axis defined by the axis of compression of the spring. The triggler and the lancet holder interact by keeping the spring of the lancet structure in a standby compressed state. Upon compression of the assembly along the longitudinal axis by the user pressing the end wall of the triggler onto the skin of a patient, the lancet will be fired to pierce the skin.

The following detailed description describes the preferred embodiment for implementing the underlying principles of the present invention. One skilled in the art should understand, however, that the following description is meant to be illustrative of the present invention, and should not be construed as limiting the principles discussed herein. In the following discussion, and in the claims the terms "including", "having" and "comprising" are used in an open-ended fashion, and thus should be interpreted to mean "including but not limited to .....".

Fig. 1 shows an embodiment of the lancet holder **26** with the side walls cut away to reveal the spring holder **36**. A spring **45a** is shown in dotted line. In this embodiment, the spring holder **36** is generally shaped into a cylinder with an open first end **102**, and a second end **104** attached to the end wall **30** of the lancet holder. Two slits **106**, running from the open first end towards the proximal end are provided on the side wall of the spring holder. In this embodiment, a wider slot **108** is further cut into the side wall of the spring holder. To strengthen the side walls of the spring holder, two ridges **112** are provided to connect the side walls of the spring holder and the lancet holder. This improves the rigidity of the spring holder, and hence the reliability and accuracy of the firing procedure. An additional pair of lugs **114** are provided at the proximal end of the spring holder juxtaposing the two sides of slot **108**. These lugs can interact with a u-shaped extension **47** in the spring. The lancet holder is preferably made from a rigid

plastic material with good mechanical strength such as polycarbonate material in order to withstand the high energy firing process of the metal spring.

Figure 2 shows detailed features of the triggler **50**. In this embodiment, the triggler is of a rectangular shape having an end wall **52** with aperture **54**. Side walls **58** extending from the four corners of end wall **52** to form a stabilizing element. The triggering means, in the form of actuating ribs **56** extend from two opposing sides of end wall **52**. A small wedge **60** is provided at the end of each actuating rib **56**. Two L-shaped clips **62** further extend from opposing sides of end wall **52**. The triggler is preferably made from a slightly flexible plastic, such as Acrylonitrile Butadiene Styrene (ABS) material to allow the actuating ribs to bend with the right resistance.

Figures 3A, 3B and 4A-D show how the lancet assembly, having a longitudinal axis **38**, a distal end **22** and a proximal end **23**, is assembled to provide the desired features. The lancet structure includes a lancet body **40**, a lancet **44** with a sharp tip **46**, and a spring **45** with a linear axis of compression. In this embodiment, spring **45** is a helical metal coil, and has a U-shaped extension **47** at the proximal end. Lancet body **40** is provided with channel **42** for receiving and securing the lancet such that the sharp tip **46** of the lancet is at the distal end. Guiding pins **48** are provided on opposing sides of body **40**.

Securing pins **49** extend from the proximal end of body **40** for securing spring **45** onto the body.

The assembled lancet structure is received within spring holder **36** with spring **45** pressed onto end wall **30** of lancet holder **26**. Guiding pins **42** are slotted into slits **106** such that lateral movement and rotational movement around the longitudinal axis is prevented. The spring **45** is fitted onto the lancet body **40** such that the U-shaped extension **47** extends through slot **108** and wraps around either one of lug **114**. This arrangement prevents the spring from being easily dislocated from the spring holder during the firing process.

The side walls **58** of triggler **50** are slidably inserted into the space between the spring holder **36** and the side walls **32** of the lancet holder such that the small wedges **60** of actuating ribs **56** slide through slits **106** and press the guiding pins towards the proximal end of the lancet holder. The L-shaped clip **62** on the triggler is adapted to engage the elongated recess **34** on the lancet holder to limit the longitudinal movement of the triggler relative to the lancet holder.

During assembly, the triggler is pressed down toward the lancet holder in the direction shown by arrow **120**, and in the process, the guiding pins, are forced down concomitantly by the small wedges on the actuating ribs. This compression force compresses the spring. As the triggler is pressed lower, the resistance of the spring to further compression becomes greater. When the resistance of the spring

exceeds the mechanical strength of the actuating ribs to push on the guiding pins, the actuating ribs are bent outwards from the longitudinal axis of the lancet holder, releasing the compression of the lancet structure and resulting in firing of the lancet.

In the preferred embodiment, a cap **66** is provided to interact with the side walls **32** of the lancet holder to maintain sterility and to protect users in cases of accidental firing. The cap is preferably an air-seal or sterile cap.

In the standby position, the resistance of the spring to compression forces clip **62** towards the distal end of recess **34**. In the most preferred embodiment, the length of actuating ribs **56** is designed to allow the end wall of the triggler to extend a short distance **41** from the side walls **32** of the lancet holder when the assembly is in the standby position, for example, 12 mm from the distal end. This short distance means that the triggler is well protected from firing due to accidental bumping. Furthermore, due to the lack of lateral movement, the direction of the external pressure has to be very close to the longitudinal axis of the assembly in order for the triggler to be compressed sufficiently for firing to occur. The mechanical strength of the actuating rib may be designed such that deformation (i.e. firing) only occurs when sufficient pressure is provided on the triggler end wall. In addition, the spring may be chosen such that triggering only occurs when the triggler is flush against the edge of the proximal end

of the lancet holder, or even pushed slightly inside. All these parameters may be varied to reduce the chance of accidental firing without undue experimentation. When the user wants to prick the finger of the patient, he presses the end wall **52** of the triggler against the skin of the finger. This compression force pushes clip **62** towards the proximal end of the recess and the triggler towards the proximal end of the lancet holder, increasing the compression of the spring. This causes the spring to generate an opposing extension force, which pushes against wedges **60** of the actuating ribs **56**. Ribs **56** are designed to bend outwards into the firing position with this additional pressure, in which wedges **60** disengages from guiding pin **48**, causing the spring to fire into a fully extended position and the lancet to jab the skin of the patient. It is clear that from the above description, the triggering mechanism is from the interaction with the patient's skin. As a result, if the patient pulls back his hand just when the user is about to press down the triggler, triggering would not occur.

The slot **108** and lug **114** at the proximal end of spring holder acts as the securing element of the spring such that after firing, the distal end of the spring recoils towards the proximal end. In this way, the sharp tip of the lancet is retracted completely back into the lancet holder after firing. This is a highly desirable safety feature.

While the present invention has been described particularly with references to the aforementioned figures, it should be understood that

the figures are for illustration only and should not be taken as limitation on the invention. It is contemplated that many changes and modifications may be made by one of ordinary skill in the art without departing from the function, spirit and the scope of the invention described, examples of which are described below.

The stabilizing element in the present invention, described as side walls **58** at the four corners of the triggler **50** in above embodiment, serves not only as a structure to allow interaction between the triggler and the lancet holder, but also a structure to prevent lateral movements therebetween. As a result, only firm compressional pressure almost directly along the longitudinal axis is required for firing to occur, and accidentally knocking the triggler in any other direction is not likely to cause firing. Besides having side walls on all four corners, other embodiments may be possible, such as rigid structures symmetrically extending from the end walls of the triggler. The tight association between the triggler and the lancet holder also means that the lancet structure is completely protected and enclosed, and it is extremely difficult to dismantle the assembly without breaking some parts.

The securing means may be other structures in the molded plastic spring holder which allows interaction of the proximal end of the spring with the proximal end of the lancet holder. This securing means allows a metallic helical spring with superior springback properties to be

used instead of plastic springs which may be fabricated as an integral part of the spring holder.

Besides a recess on the interior side wall of the lancet holder, other structures, such as an elongated aperture or a bracket in the side wall may also serve as the mating element. A structure which is only accessible from the interior is, however, preferred as it prevents external tampering.

What is claimed is :

1. A lancet assembly comprising :

a lancet structure comprising

a body having a proximal end and a distal end and a guiding element;

a lancet with a sharp tip, attached to said body, such that the sharp tip extend from the distal end of said body; and

a spring coupled to and extending from the proximal end of said body, said spring having a linear axis of compression;

a lancet holder comprising

an open distal end;

an end wall at the proximal end;

side walls with mating means, extending from said end wall,

a spring holder having

an open first end,

a second end attached to said end wall; and

supporting structures therebetween defining an interior space, said lancet structure received within said interior space with said sharp tip proximate said open first end, said supporting structure further provided with receiving means for engagement with said guiding elements to allow movement of said body along the axis of compression;

a triggler, inserted into said holder, said triggler comprising

a triggler end wall for closing said distal end of said holder and having an aperture wherethrough said sharp distal tip of said lancet fires when triggered;

a stabilizing element, extending from said triggler end wall and inserted between said side walls and said supporting structures for sliding movement along the axis of compression, said stabilizing element further limiting movement of said triggler lateral to said axis of compression;

a safety catch, engaging said mating means of said holder, for maintain said triggler between the standby and firing positions; and

a triggering means, for engagement with said guiding element, said triggering means in the standby position maintaining said spring in a high potential energy compressed state by forcing said guiding element towards the proximal end of said holder, said triggering means further movable to said firing position when external compression pressure is applied to said triggler end wall, said trigger means in said firing position being disengaged from said guiding element such that said spring is released from said compressed state and the sharp distal end of said lancet structure is fired through said aperture of said triggler end wall.

2. A lancet assembly according to claim 1 wherein said lancet holder further comprises a securing means for securing the proximal end of said spring to the proximal end of said lancet holder.

3. A lancet assembly according to claim 2 wherein said securing means is at least one lug provided on the external surface of said spring holder proximate said end wall; said lug engaging an extension of said spring on the proximal end for coupling to said lug.

4. A lancet assembly according to claim 3 wherein said spring holder further comprises a slot along the length of said supporting structures wherethrough said extension of said spring can access the lug for coupling.

5. A lancet assembly according to claim 1 wherein said guiding element comprises guiding pins extending laterally from at least two opposing sides of said body.

6. A lancet assembly according to claim 5 wherein said receiving means are longitudinal slits within said supporting wall wherethrough said guiding pins extend.

7. A lancet assembly according to claim 1 wherein said safety catch comprises L-shaped clips extending from two opposing sides of said triggler end wall, and said mating means comprises recesses in the interior of said side wall of said lancet.

8. A lancet assembly according to claim 1 wherein said triggering means comprises a pair of actuating ribs with wedged ends extending from two opposing sides of said triggler end wall; and said guiding element

comprises a pair of guiding pins extending laterally from two opposing sides of said body, said triggler inserted into said lancet holder such that said wedged ends engage said guiding pins, said actuating rib in the armed position maintaining said spring in a high potential energy compressed state by forcing said guiding pin towards the proximal end of said lancet holder, said actuating rib further bendable to said firing position when external compression pressure is applied to said triggler end wall.

9. A lancet assembly according to claim 1 wherein said lancet holder further comprising ridges attached to said spring holder and said lancet holder to strengthen said supporting structure.

10. A lancet assembly according to claim 1 further comprising a air-seal cap for covering up said aperture and maintaining sterility.

11. A lancet assembly comprising :

a lancet structure comprising

a body having a proximal end, a distal end and a longitudinal axis;

a lancet having a sharp tip, said lancet attached to said body such that the lancet extend from the distal end of said body;

a plurality of guiding pins extending laterally opposing sides said body; and

a helical metallic spring coupled to said body and extending from the proximal end along said longitudinal axis;

a lancet holder comprising

a rectangular open distal end;

a rectangular end wall at the proximal end;

four side walls extending from said end wall with two opposing side walls having a recess on the interior surface;

a spring holder having

an open first end,

a second end attached to and extending from said end wall; and

supporting wall therebetween defining a substantially cylindrical interior space, said lancet structure received within said interior space with said sharp tip proximate said open first end, the dimensions of said cylindrical space limiting the lateral movement of said lancet structure, said supporting wall provided with slits wherethrough said guiding pins extend to allow longitudinal movement of said lancet structure;

a triggler, inserted into said holder, said triggler comprising

a triggler end wall for closing said distal end of said holder; said triggler end wall substantially parallel to said axis of compression and having an aperture wherethrough said sharp distal tip of said lancet fires when triggered;

triggler side walls extending from the four corners of said triggler end wall and inserted between said side walls of said lancet holder and said supporting wall for sliding movement along the longitudinal axis while limiting lateral movement of said triggler;

an L-shaped safety catch, extending from said triggler end wall and engaging said recess of said holder, for maintain said triggler inside said lancet holder between an standby position and a firing position; and

a pair of actuating ribs with wedged ends, extending from said triggler end wall, for engagement with said guiding pins, said actuating rib in the standby position maintaining said spring in a high potential energy compressed state by forcing said guiding element towards the proximal end of said lancet holder, said actuating rib further bendable to said firing position when external compression pressure is applied to said triggler end wall, said wedge in said firing position being disengaged from said guiding pin such that said spring is released from said compressed state and the sharp distal end of said lancet structure is fired through said aperture of said triggler end wall.

12. A lancet assembly according to claim 1 further comprising a cap for covering up said aperture.

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