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Schraga

(10) **Patent No.: US 8,814,896 B2**
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(54) **SINGLE USE LANCET ASSEMBLY**

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This patent is subject to a terminal disclaimer.

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Related U.S. Application Data

(63) Continuation-in-part of application No. 13/270,525, filed on Oct. 11, 2011, now Pat. No. 8,353,924, which is a continuation of application No. 12/786,112, filed on May 24, 2010, now Pat. No. 8,034,069, which is a continuation of application No. 10/894,865, filed on Jul. 20, 2004, now abandoned, which is a continuation-in-part of application No. 09/903,877, filed on Jul. 10, 2001, now Pat. No. 6,764,496, which is a continuation-in-part of application No. 09/432,351, filed on Nov. 2, 1999, now Pat. No. 6,258,112.

(51) **Int. Cl.**
A61B 17/34 (2006.01)

(52) **U.S. Cl.**
USPC **606/182**

(58) **Field of Classification Search**
CPC A61B 5/1411; A61B 5/15142; A61B 5/15144; A61B 5/150519; A61B 5/150885; A61B 5/15; A61B 5/151
USPC 606/181–183, 167, 170, 184, 185; 600/583
See application file for complete search history.

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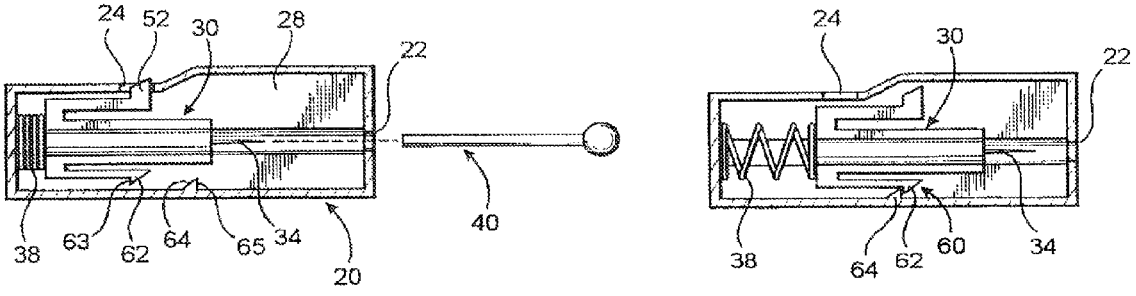
Primary Examiner — Kathleen Holwerda
(74) *Attorney, Agent, or Firm* — Malloy & Malloy, P.L.

(57) **ABSTRACT**

A single use lancet device having a housing, with an open interior and an access opening defined therein, a lancet, with a body and a piercing tip, and disposed in the open interior of the housing so as to move between a cocked orientation and a piercing orientation, a driving assembly structured to move the lancet into the piercing orientation, and a restrictor assembly having a shoulder element and a restrictor panel operatively associated with the lancet and the housing and structured to pass over the restrictor panel upon the lancet moving from its cocked orientation to its piercing orientation, and to abut the restrictor panel upon attempted movement of the lancet back into its cocked orientation after movement into the piercing orientation, thereby preventing the lancet from moving back into the cocked orientation and preventing reuse of a contaminated piercing tip.

4 Claims, 1 Drawing Sheet



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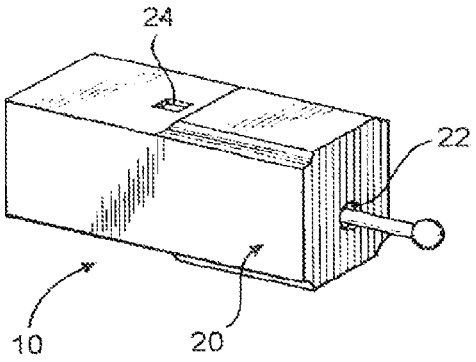

FIG. 1

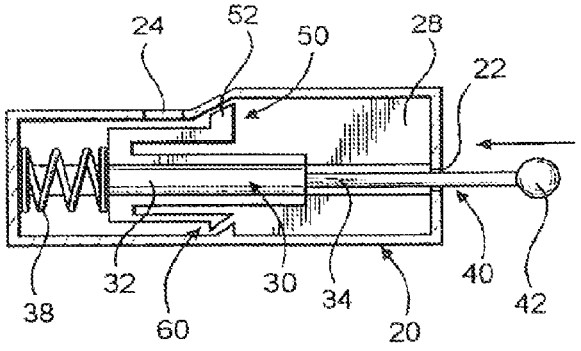

FIG. 2

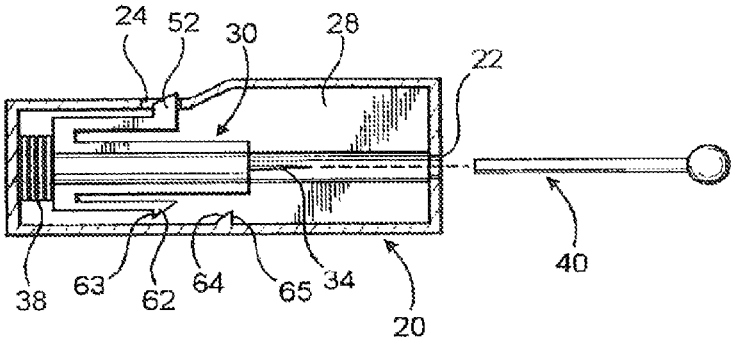

FIG. 3

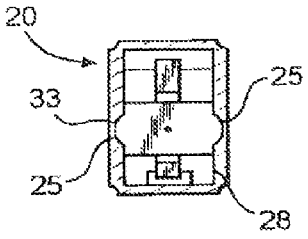

FIG. 5

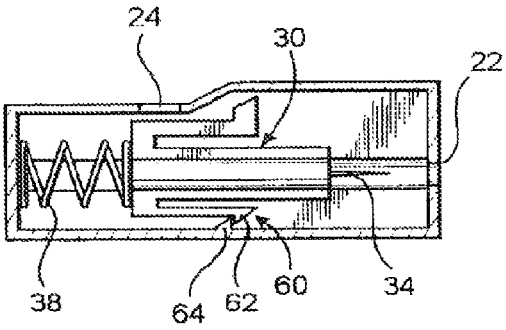

FIG. 4

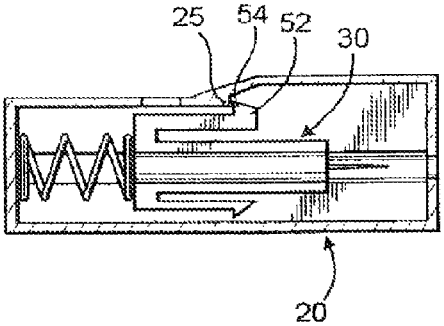

FIG. 6

SINGLE USE LANCET ASSEMBLY

CLAIMS OF PRIORITY

The present patent application is a Continuation of patent application having Ser. No. 13/270,525 filed on Oct. 11, 2011, which is a Continuation of patent application having Ser. No. 12/786,112 filed on May 24, 2010 which matured into U.S. Pat. No. 8,034,069 on Oct. 11, 2011, which is a Continuation of patent application having Ser. No. 10/894,865 filed on Jul. 20, 2004 now abandoned, which is a Continuation-In-Part application of U.S. patent application having Ser. No. 09/903,877 which was filed on Jul. 10, 2001 which matured into U.S. Pat. No. 6,764,496 on Jul. 20, 2004, which is a continuation-in-part patent application having Ser. No. 09/432,351 which was filed on Nov. 2, 1999 and which issued as U.S. Pat. No. 6,258,112 on Jul. 10, 2001, now abandoned, are hereby incorporated by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to a single use lancet assembly which is substantially compact, yet effective for piercing a patient's finger or other body part to obtain a blood sample. The single use lancet device is further configured to be substantially safe to transport and to ensure that subsequent uses of a contaminated lancet tip cannot occur.

2. Description of the Related Art

Lancets are commonly utilized instruments which are employed both in hospitals and other medical facilities, as well as by private individuals, such as diabetics, in order to prick or pierce a patient's skin, typically on a finger of a patient, thereby leading to the generation of a blood sample which can be collected for testing. Because of the wide spread use of such lancets, there are a variety of lancet devices which are available for utilization by patients and/or practitioners in a variety of different circumstances.

For example, a typical lancet may merely include a housing with a sharp piercing tip that is pushed into the patient's skin. More commonly, however, lancet devices, which house a piercing tip and/or a lancet, have been developed which effectively encase and fire the lancet into the patient's skin, thereby eliminating the need for the person taking the sample to actually push the lancet tip into the skin.

Within the various types of specialized lancet devices, one variety is typically configured for multiple and/or repeated uses, while another category is particularly configured for single use, after which the entire device is disposed of. Looking in particular to the single use, disposable lancet devices, such devices typically include a housing which contains and directs or drives a piercing tip into the patient's skin, and which is disposed of along with the used lancet. Naturally, so to make such disposable devices cost effective for frequent use, such devices tend to be rather simplistic in nature providing only a sufficient mechanism for firing, and not overly complicating the design so as to minimize that cost.

While existing single use devices are generally effective for achieving the piercing of the skin required for effective operation, such single use, disposable devices typically do not incorporate a large number of safety features to ensure the safe use and disposal of the device. For example, one primary area of safety which must be addressed with all lancet devices pertains to the purposeful and/or inadvertent reuse of a contaminated lancet. Unfortunately, most currently available single use lancet devices are configured such that after a use

thereof has been achieved, it is possible for a patient to recock the device, thereby allowing for a subsequent, inappropriate use.

As a result, it would be highly beneficial to provide a single use lancet device which is substantially compact and disposable, can be manufactured in a substantially cost effective manner, and which nevertheless is substantially safe to utilize, affirmatively preventing re-use, once contaminated.

SUMMARY OF THE INVENTION

The present invention relates to a single use lancet device configured to pierce a patient's skin and be useable only a single time, thereby preventing reuse of a contaminated lancet piercing tip. In particular, the present single use lancet device includes a housing having an open interior area and an access opening defined therein. The housing is preferably compact and includes a lancet disposed within its open interior.

Looking to the lancet, it is preferably of the type which includes a body and a piercing tip. It is the piercing tip which includes the pointed configuration structured to penetrate or pierce a patient's skin for the drawing of blood. Moreover, the lancet is cooperatively disposed within the open interior of the housing such that the lancet may move between at least a cocked orientation and a piercing orientation wherein the patient's skin is penetrated by the piercing tip.

Also operatively associated with the lancet is a driving assembly. The driving assembly is structured to move or drive the lancet, at least temporarily, into the piercing orientation from the cocked orientation. Preferably, however, the device is configured such that the cocked orientation is generally maintained until affirmatively released by a user. Along these lines, the present single use lancet device also includes an actuation button operatively associated with the lancet. The actuation button is structured to protrude from the housing, at least when the lancet is disposed in the cocked orientation, so as to be effectively actuatable. When the lancet is in the cocked orientation, the actuation assembly maintains the lancet in that cocked orientation, however, when it is actuated, such as by being pushed inward, the lancet is released from the cocked orientation and the driving assembly propels the lancet at least temporarily into its piercing orientation wherein the piercing tip protrudes through the access opening of the housing.

In order to ensure that lancet device can only be used a single time, the present single use lancet device further includes an abutment structure cooperatively disposed between the housing and the lancet. The abutment structure is configured to prevent the lancet from moving into the cocked orientation after movement into the piercing orientation. Preferably, the abutment structure includes a shoulder element and a restrictor panel operatively associated with the lancet and the housing. In particular, the shoulder element is structured to pass over the restrictor panel when the lancet moves from its cocked orientation to its piercing orientation. Conversely, however, when a user attempts to move the lancet back into the cocked orientation after it moved into the piercing orientation, the restrictor panel abuts the shoulder element preventing further movement. As a result, movement of the lancet into the cocked orientation is prevented once the lancet has been used a single time, and subsequent uses of a contaminated lancet are prevented.

These and other objects, features and advantages of the present invention will become clearer when the drawings as well as the detailed description are taken into consideration.

BRIEF DESCRIPTION OF THE DRAWINGS

For a fuller understanding of the nature of the present invention, reference should be had to the following detailed description taken in connection with the accompanying drawings in which:

FIG. **1** is a perspective illustration of an embodiment of the single use lancet device of the present invention;

FIG. **2** is a side cross section view of the single use lancet device of the present invention in an unused, initially un-cocked orientation;

FIG. **3** is a side cross section view of the single use lancet device of the present invention in a cocked orientation;

FIG. **4** is a side cross section view of the single use lancet device of the present invention after it has moved into a piercing orientation from the cocked orientation;

FIG. **5** is a front cross section view of the single use lancet device of the present invention; and

FIG. **6** is a side cross section view of another embodiment of the single use lancet device of the present invention after the lancet has moved from the cocked orientation through the piercing orientation.

Like reference numerals refer to like parts throughout the several views of the drawings.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Shown throughout the Figures, the present invention is directed towards a single use lancet device, generally indicated as **10**. In particular, the single use lancet device **10** of the present invention includes a housing, generally indicated as **20**. The housing **20** is preferably substantially small and compact, and may be made of one or a plurality of segments, preferably of a generally rigid, disposable material, such as plastic. The housing **20** includes an at least partially open interior **28** and at least one access opening **22** defined therein. The open interior **28** of the housing **20** is preferably sized and configured to effectively receive a lancet, generally **30** therein.

In particular, the lancet device **10** of the present invention also comprises a lancet **30**. The lancet **30** preferably includes a body **32** and a piercing tip **34**. The piercing tip **34** is what will be used to pierce a person's skin so as to draw blood to be utilized for a sample and or test procedure. Moreover, the body **32** may be the shaft of the piercing tip **34** and/or an additional structure such as that depicted in the Figures. Regardless, however, the lancet **30** is structured to move within the open interior **28** of a housing **20**, preferably at least between a cocked orientation, as depicted in FIG. **3**, and a piercing orientation wherein the piercing tip **34** of lancet **30** at least temporarily protrudes through the access opening **22**.

Looking in further detail to the illustrated lancet device **10**, and the path of movement of the lancet **30** within the housing **20**, when the lancet device **10** is initially obtained for use, the lancet **30** is preferably maintained in an un-used, initially un-cocked and pre-fired orientation, as best seen in FIG. **2**. In this initially un-cocked and pre-fired orientation a protective cover **40** preferably extends into the open interior **28** of the housing **20** so as to at least partially and removably cover the piercing tip **34** of the lancet **30**, thereby maintaining the safety and sterility of the piercing tip **34** when not being used. In this regard, the protective cover **40** may be formed from a variety of preferably rigid materials and is structured to protrude from the housing **20**. Furthermore, the protective cover **40** may include an enlarged head **42** configured to facilitate grasping thereof.

Preferably utilizing the protective cover **40**, the protective cover **40** is structured to be pushed inwardly into the housing by a user, as depicted by the arrows on FIG. **2**, thereby pushing the lancet **30** further into the housing **20**. Such pushing of the lancet **30** into the housing **20** results in a positioning of the lancet **30** in its cocked orientation, best illustrated in FIG. **3**. Once in the cocked orientation, the protective cover **40** is then structured to be removable from the piercing tip **34**, such as by a twisting thereof, thereby leaving the piercing tip **34** completely exposed for use.

The single use lancet of the present invention further includes a driving assembly, generally indicated as **38**. The driving assembly **38** is particularly configured to move the lancet **30** at least temporarily into its piercing orientation wherein the piercing tip **34** protrudes through the access opening **22** of the housing **20** a desired amount. In particular, if desired, a depth adjustment structure could be positioned at the access opening **22** to control the amount which the piercing tip protrudes from the housing **20**. For example, a threaded washer type element could be adjustably secured to the housing **20** in generally surrounding relation to the access opening **22**.

Looking further to the driving assembly **38**, preferably the driving movement occurs when the lancet **30** is released from its cocked orientation. In the illustrated embodiment, the driving assembly **38** includes a biasing element operatively disposed between the lancet **30** and the housing **20**. Moreover, in the illustrated embodiment a spring is preferably utilized, however, it is recognized that a variety of other driving assemblies can be utilized, including a wedge assembly, a hammer type assembly and/or a resilient material plate, segment or extension, all of which may be configured to move the lancet **30** from the cocked orientation into the piercing orientation. Further, it is preferred, based upon the sizing of the housing **20** and the nature and size of the driving assembly **38**, that after the lancet **30** has moved into the piercing orientation, wherein the piercing tip **34** protrudes through the access opening **22**, the lancet tends to be retracted back into the open interior **28** of the housing **20**, as best illustrated in FIG. **4**. As a result, the used piercing tip **34** is effectively concealed within the housing **20** subsequent to usage, protecting against inadvertent engagement between a person and the used piercing tip **34**.

In order to retain, and subsequently effectively release the lancet **30** from its cocked orientation, the single use lancet of the present invention further includes an actuation assembly, generally indicated as **50**. Although a variety of different actuation assemblies may be incorporated so as to retain and then release the lancet **30** from its cocked orientation, which in the illustrated embodiment allows the driving assembly to be released from its compressed orientation, the actuation assembly includes an actuation button **52**. In the illustrated embodiment, the actuation button **52** is structured to at least temporarily protrude from the housing **20**, such as through an actuation aperture **24**. Furthermore, the actuation button **52** is preferably secured, either directly or indirectly to the lancet **30**, so as to generally restrict movement of the lancet **30** from the cocked orientation when the actuation button **52** protrudes from the housing **20**. As a result, the cocked orientation is maintained while the actuation button protrudes from the housing **20**. Specifically, in the illustrated embodiment, the actuation button **52** extends from the body **32** of the lancet **30** by a biased segment, and as such, by abutting the housing **20** within the actuation opening **24**, movement of the lancet **30** from the cocked orientation is prevented. When, however, the actuation button **52** is actuated, such as by being pushed inwardly into the interior **28** of the housing **20**, it is at least

temporarily concealed within the housing **20**, removing its abutting engagement with the housing and allowing the lancet **30** to freely move within the housing **20**, at least temporarily into the piercing orientation. Although the preceding defines the illustrated actuation assembly, it is understood that a variety of alternative actuation assemblies, such as including separate elements to retain and to release the lancet may also be provided, and or including structures which are actually part of the driving assembly and/or remain at least partially exposed and actuatable at all times, may also be provided.

Looking in particular to FIG. **5**, movement of the lancet **30** through the housing **20** is preferably maintained in a substantially linear path by a guide assembly. In the illustrated embodiment, the guide assembly includes at least one guide ridge **33** protruding from the body **32** of the lancet **30**, and at least one corresponding guide track **25** structured to movably receive the guide ridge **33** therein. The guide track **25** preferably extends at least partially along a length of the open interior **28** of the housing **20** so as to maintain the guide ridge **33** effectively therein during a necessary range of motion of the lancet **30**. As depicted in FIG. **5**, preferably a pair of guide ridges **33** are disposed on opposite sides of the lancet body **32**, with a corresponding pair of oppositely disposed guide tracks **25** being defined in the housing. It is of course, however, understood that the guide tracks **25** need not necessarily be directly defined in the housing **20**, but may be additional elements secured therein, and conversely the guide track(s) may be defined in or on the lancet body **32**, with the guide ridge(s) extending inwardly from the housing **20**.

The single use lancet **10** of the present invention further includes a restrictor assembly, generally indicated as **60**. The restrictor assembly **60** is structured to substantially prevent the lancet **30** from moving back into the cocked orientation of FIG. **3** after it has moved, even momentarily, into the piercing orientation wherein a patient's skin may be pierced and the piercing tip **34** becomes contaminated. In this regard, the cocked orientation may be defined by the lancet **30** being positioned such that actuation of the actuation assembly **50** causes the driving assembly **38** to urge the lancet **30** into the piercing orientation. In the illustrated embodiment, the restrictor assembly **60** is structured such that when the lancet **30** is disposed in the initially un-cocked orientation, as best seen in FIG. **2**, movement of the lancet **30** back into the cocked orientation can effectively result despite the restrictor assembly **60**. After, however, the lancet **30** has moved into its piercing orientation wherein the piercing tip **34** has protruded through the access opening **22** of the housing **20**, the restrictor assembly **60** is configured such that the lancet **30** can no longer be pushed back into the cocked orientation. As a result, a patient can neither accidentally nor purposefully reuse the single use lancet **10** of the present invention after it has been fired.

In the illustrated embodiment, the restrictor assembly **60** includes an abutment structure cooperatively disposed between the housing **20** and the lancet **30**. The abutment structure is configured to physically prevent movement of the lancet back into the cocked orientation. Preferably, the abutment structure comprises a shoulder element **62** and a restrictor panel **64** configured to freely pass one another when the lancet **30** moves from the cocked orientation to the piercing orientation, but also configured to abut one another upon attempted movement of the lancet **30** back into the cocked orientation after it has moved into the piercing orientation. Looking to FIG. **4**, the illustrated shoulder element **62** includes an at least partially sloped and preferably biased configuration, such as an elongate biased finger that at least partially retracts inward towards the body **32** of the lancet **30** so as to facilitate passage thereof past the restrictor panel **64**. In this regard, preferably mating sloped surfaces are provided on the shoulder element **62** and the restrictor panel **64**, thereby facilitating the sliding passages past one another, and indeed, promoting an at least partial retraction of the shoulder element to further facilitate this passage past one another, upon movement of the lancet **30** in a first direction towards the access opening **22** of the housing **20**. The shoulder element **62** is also, however, structured to generally expand after it has passed the restrictor panel **64**, such as back into its normal unretracted and/or un-compressed orientation, such that it will abut the restrictor panel **64** upon attempted movement of the lancet **30** in a second direction opposite the access opening **22** of the housing **20**.

Although an opposite configuration could be just as effectively utilized, in the illustrated embodiment, the biased finger of the shoulder element **62** extends from the lancet **30**, preferably generally toward the piercing tip **34** of the lancet **30**, while the restrictor panel **64** protrudes from the housing **20**, extending into the open interior **28** of the housing **20**. Along these lines, the restrictor panel **64** includes a protruding element preferably with the aforementioned sloped configuration which downwardly slopes away from the piercing tip **34** of the lancet **30** facilitating the aforementioned sliding passage past the shoulder element **62**.

So as to provide generally secure movement restriction through effective abutment, both the shoulder element **62** and the restrictor panel **64** each preferably include abutment surfaces **63** and **65**, respectably. The abutment surfaces **63** and **65** are structured to generally engage and abut one another, as best illustrated in FIG. **4**, thereby preventing movement of the lancet **30** back into the cocked orientation. In the illustrated embodiment, the abutment surfaces **63**, **65** are generally flat, although it is recognized that interlocking fingers or wedges, and/or other types of engaging structures that prevent relative movement in at least one direction could also be effectively utilized.

Addressing further the restrictor assembly of the present invention, it is understood that a variety of different restrictor assemblies may be effectively utilized which prevent movement of a lancet **30** back into a cocked orientation after the lancet **30** has moved sufficiently forward and/or has moved into the piercing orientation. As such, the embodiment illustrated in FIGS. **2** through **5** is merely a single illustration of a preferred contemplated embodiment, and other alternative embodiments are also considered within the scope of the restrictor assembly of the present invention. By way of example, and looking specifically to FIG. **6**, the actuation button **52** may comprise part of the restrictor assembly. In such an embodiment, a restrictor panel **25** is defined in the housing **20**, and the actuation button **52** as part of the biased finger of the shoulder element, includes an abutment surface **54** which engages a confronting surface of the restrictor panel **25**. In such an embodiment, the initially un-cocked orientation provides for the actuation button **52** to be initially disposed rearward of the restrictor panel **25** so as to permit movement of the lancet **30** at least initially into the cocked orientation. Moreover, in this embodiment, the previous embodiment, and/or any other alternative embodiment, if desired, the protective cover **40** may be equipped with an interior shield segment or other configuration which extends into the housing and maintains the biased finger of the shoulder element **62**, or another component of the restrictor assembly, in a generally compressed and/or retracted orientation until the protective cover **40** is removed. As a result, in such an embodiment, so long as the protective cover **40** is maintained on the piercing tip **34**, the lancet **30** is always able to return the

cocked orientation. Preferably, however, re-positioning of the protective cover onto the piercing tip in such a manner as to be able to "reset" the lancet **30**, allowing its movement once again into the cocked orientation, will be prevented.

Since many modifications, variations and changes in detail can be made to the described preferred embodiment of the invention, it is intended that all matters in the foregoing description and shown in the accompanying drawings be interpreted as illustrative and not in a limiting sense. Thus, the scope of the invention should be determined by the appended claims and their legal equivalents.

Now that the invention has been described.

What is claimed is:

1. A single use lancet device comprising:

a housing;

a lancet having a piercing tip;

said lancet moveable relative to said housing at least between a cocked orientation and a piercing orientation;

a biasing element structured to bias said lancet at least temporarily into said piercing orientation;

a restrictor, at least part of said restrictor being independent of said biasing element and said lancet, and when engaged, said restrictor being structured to prevent said lancet from moving back into said cocked orientation, after movement of said lancet into said piercing orientation, as a result of an implement contacting and pushing said lancet;

said restrictor comprising an abutment structure including a biased finger having a shoulder element and a restrictor panel including a protruding element;

said protruding element including a sloped configuration structured to facilitate passage thereof past said biased finger upon said lancet moving to said piercing orientation;

said restrictor panel and said shoulder element structured to pass one another upon said lancet moving from said cocked orientation to said piercing orientation and to abut one another upon attempted movement of said lancet into said cocked orientation after movement into said piercing orientation; and

at least one of said shoulder element and said restrictor panel structured to retract out of a normal unretracted orientation during passage past one another and to expand back to said normal unretracted orientation after passage past one another, so as to facilitate passage of said restrictor panel and said shoulder element past one another in a first direction corresponding to movement of said lancet from said cocked orientation to said piercing orientation and to block movement of said restrictor panel in a second direction, generally opposite to the first direction, subsequent to said passage past one another in the first direction.

2. A single use lancet as recited in claim **1** wherein said biasing element comprises a spring.

3. A single use lancet as recited in claim **1** further comprising an actuator, said actuator including a button structured to protrude from said housing when said lancet is disposed in said cocked orientation.

4. A single use lancet as recited in claim **1** further comprising a protective cover structured to at least partially and removably cover said piercing tip of said lancet at least prior to movement of said lancet into said cocked orientation.

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