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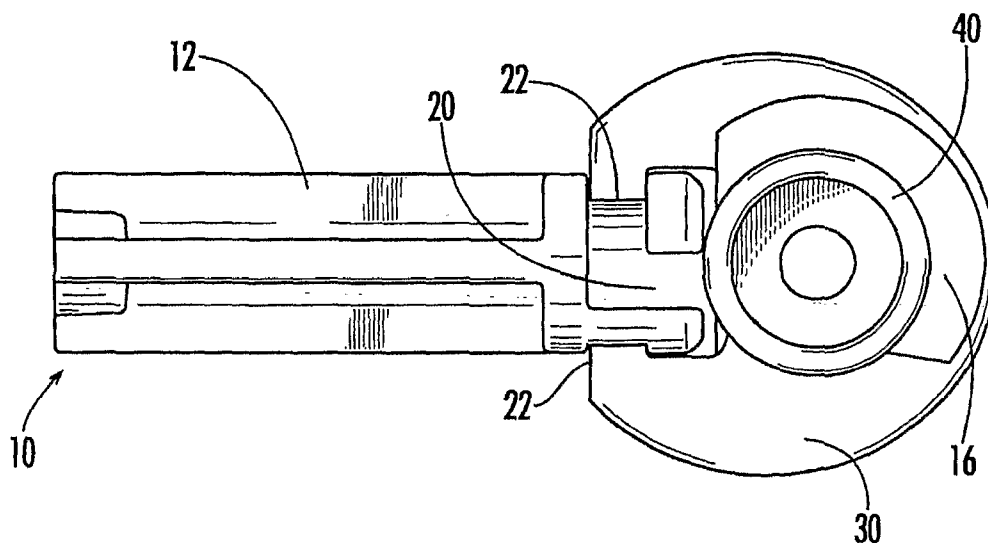
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(54) Title: LANCET WITH CAP-REMOVAL GUIDANCE



(57) Abstract: A lancet having a body portion, a sharp tip element, a removable endcap, the endcap and the body portion including cooperating guidance features to maintain alignment of the endcap and prevent damage to the tip element during removal of the endcap, an indicator to distinguish a new lancet from a used lancet, and a gripping surface on the endcap for facilitating removal.

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LANCET WITH CAP-REMOVAL GUIDANCE

Cross-Reference to Related Application

[0001] This application claims the benefit of U.S. Provisional Patent Application Serial No. 60/763,671, filed January 31, 2006, the entirety of which is hereby incorporated herein by reference for all purposes.

Technical Field

[0002] The present invention relates generally to a lancet for body fluid sampling, and more particularly to a lancet having a protective endcap with guidance features to prevent damaging the lancet needle upon cap removal.

Background of the Invention

[0003] Lancets are commonly used to penetrate the skin of a subject and obtain a sample of blood or other body fluid, as in the testing of blood sugar levels by diabetics or in blood-typing. A lancet is often mounted in a lancing device for carrying the lancet and/or driving the lancet along a path of travel to penetrate the skin. One or more lancet(s) can be permanently mounted within a "disposable" or "single-use" lancing device, or can be removably and replaceably installed in a "multi-use" lancing device. Alternatively, a lancet can be manually held for pricking the skin during sampling.

[0004] Lancets typically include a sharp tip element comprising a metal needle or blade for pricking the skin, and a body of plastic or other material for carrying the tip element. A removable endcap may be provided to maintain sterility of the tip element, and to protect against inadvertent sticks with the sharp tip element. The endcap is commonly formed of plastic, and may be integrally molded as an extension of the lancet body or may be a separate component. The endcap is typically removed prior to the lancing procedure, and optionally is replaced after use of the lancet to reduce the likelihood of needle sticks or contamination by a disposed lancet.

[0005] Improvements to blood-glucose sampling devices have greatly reduced the fluid sample size needed for testing in many instances. This is advantageous,

because finer gauge (i.e., thinner) lancet tip elements can be used to generate the requisite sample size, which reduces the pain resulting from the lancing procedure. Reduced pain generally leads to increased compliance with a prescribed sampling regimen in many subjects, leading to improved maintenance of blood sugar and better health.

[0006] The finer-gauge needles used in such lancets, however, are increasingly susceptible to damage during loading and use. In particular, it has been found that finer-gauge needles may be more easily bent or broken during removal of the endcap from a lancet. Even if a needle is not broken, a bent needle can render the lancet useless, or can inflict greater than necessary pain during lancing.

[0007] Additionally, because it is not uncommon for users of lancets to suffer from reduced visual acuity and/or impaired manual dexterity, many users find it difficult to remove and replace the endcaps of previously known lancets without damaging the lancet needle.

[0008] Many users also find it difficult to distinguish between a new lancet and a used lancet with its endcap replaced after use. For example, some lancets have a removable endcap that is replacable onto the lancet after use in the same or similar position and orientation as the endcap of an unused lancet. When there is little or no visible difference between a used lancet and a new lancet, users may unwittingly reuse a potentially contaminated lancet, or may dispose a new lancet thinking it to be used.

[0009] Accordingly it can be seen that needs exist for an improved lancet and for improved lancing devices that incorporate lancets, which improvements reduce the incidence of damage to finer-gauge lancet tip elements during endcap removal and/or replacement. Needs further exist for such improvements that facilitate endcap removal and replacement, even by users with reduced visual acuity or impaired manual dexterity. Needs further exist for such improvements that better allow a user to distinguish between a new lancet and a used lancet. It is to the provision of improvements meeting any or all of these and other needs that the present invention is primarily directed.

Summary of the Invention

[00010] In example forms, the present invention provides an improved lancet that reduces the incidence of damage to finer-gauge lancet tip elements during endcap removal and/or replacement. Other example forms of the invention provide a lancet having an endcap that is easier to remove and replace. Other example forms of the invention provide a lancet that better distinguishes a used lancet from a new lancet. The invention also encompasses various forms of lancing devices incorporating one or more improved lancets, as described.

[00011] In one aspect, the present invention is a lancet having a body portion, a sharp tip element, and a removable endcap. The endcap and the body portion preferably include cooperating guidance features to maintain alignment of the endcap and prevent damage to the tip element during removal of the endcap.

[00012] In another aspect, the invention is a lancing device including at least one lancet and a spring-biased or otherwise actuated drive mechanism for propelling the lancet along a path of travel. The lancet preferably includes a body portion, a sharp tip element, and a removable endcap. The endcap and the body portion preferably include cooperating guidance features to maintain alignment of the endcap and prevent damage to the tip element during removal of the endcap.

[00013] In still another aspect, the invention is a method of preventing damage to a tip element of a lancet. The method preferably includes providing a body portion and an endcap portion of the lancet with cooperating guidance features to maintain alignment of the endcap with the body portion during removal of the endcap.

[00014] In another aspect, the invention is a lancet including, without limitation, a body portion, a sharp tip element extending in an axial direction from the body portion, and an endcap removably covering the tip element. The endcap and the body portion comprise cooperating guidance features to maintain alignment of the endcap along a path in the axial direction and prevent damage to the tip element during removal of the endcap.

[00015] In another aspect, the invention is a lancet including, without limitation, a lancet body, a sharp lancet tip projecting from the lancet body, an endcap, and an indicator for distinguishing a used lancet from a new lancet. The endcap has an initial point of attachment for covering the sharp lancet tip when the endcap is attached to the lancet body in a first orientation, and is selectively removable from the lancet body to expose the sharp tip.

[00016] In another aspect, the invention is a lancet including, without limitation, a lancet body, a sharp lancet tip projecting from the lancet body in an axial direction, and an endcap initially attached to the lancet body to cover the sharp lancet tip. The endcap is removable in the axial direction to expose the sharp lancet tip, and the endcap includes at least one gripping surface oriented in a direction generally perpendicular to the axial direction to facilitate removal of the endcap from the lancet body.

[00017] These and other aspects, features and advantages of the invention will be understood with reference to the drawing figures and detailed description herein, and will be realized by means of the various elements and combinations particularly pointed out in the appended claims. It is to be understood that both the foregoing general description and the following brief description of the drawings and detailed description of the invention are exemplary and explanatory of preferred embodiments of the invention, and are not restrictive of the invention, as claimed.

Brief Description of the Drawings

[00018] FIGURES 1A-1C show a lancet according to an example embodiment of the present invention.

[00019] FIGURES 2A-2C show a lancet according to another example embodiment of the present invention.

[00020] FIGURES 3A-3C show a lancet according to another example embodiment of the present invention.

[00021] FIGURES 4A-4D show a lancet according to another example embodiment of the present invention.

[00022] FIGURES 5A-5C show a lancet according to another example embodiment of the present invention.

Detailed Description of Example Embodiments

[00023] The present invention may be understood more readily by reference to the following detailed description of the invention taken in connection with the accompanying drawing figures, which form a part of this disclosure. It is to be understood that this invention is not limited to the specific devices, methods, conditions or parameters described and/or shown herein, and that the terminology used herein is for the purpose of describing particular embodiments by way of example only and is not intended to be limiting of the claimed invention. Also, as used in the specification including the appended claims, the singular forms "a," "an," and "the" include the plural, and reference to a particular numerical value includes at least that particular value, unless the context clearly dictates otherwise. Ranges may be expressed herein as from "about" or "approximately" one particular value and/or to "about" or "approximately" another particular value. When such a range is expressed, another embodiment includes from the one particular value and/or to the other particular value. Similarly, when values are expressed as approximations, by use of the antecedent "about," it will be understood that the particular value forms another embodiment.

[00024] With reference now to the drawing figures, FIGS. 1A-1C show a lancet 10 according to a first example embodiment of the invention. The lancet 10 preferably includes a body portion 12, a sharp blade or needle tip element 14 projecting axially from a proximal end of the body portion, and a protective endcap 16 initially covering the tip element. The tip element 14 is preferably a relatively thin or fine-gauge member, such as for example a 30-gauge or smaller needle, having a sharpened distal tip. The endcap 16 is preferably removable from the body portion 12 to expose the sharp tip element 14 for use, and replaceable thereon after use. The body portion 12 of the lancet can comprise an external geometry similar to that of a standard lancet, so that the lancet is compatible with existing lancing devices. Alternatively, the external geometry of the body portion 12 can be irregular or unique, so that only lancing devices designed for compatibility with the lancet 10 of the present invention will accept the

lancet. The lancet of the present invention is optionally produced using traditional insert molding methods, for high-volume, low cost manufacturing.

[00025] The lancet 10 preferably comprises one or more guidance features to maintain axial alignment of the endcap (and/or other sterility feature) with the body portion during removal (i.e., the endcap is guided for removal parallel to the axis of the tip element 14), thereby reducing off-axis forces typically responsible for lancet needle damage. In one example embodiment shown in FIGS. 1A-1C, the guidance features comprise two (or more) guidance channels 20 formed along the sides of the body portion 12, and two (or more) cooperating guidance fingers 22, with each guidance finger being releasably engaged within a corresponding one of the guidance channels. In the depicted embodiment, the guidance channels are generally L-shaped, having a first portion extending generally circumferentially around the sidewall of the lancet body, and a generally perpendicular second portion extending generally axially from the first portion of the channel to the proximal end of the body. The guide channels are preferably approximately equidistantly spaced about the circumference of the body portion, such that in the example embodiment having a pair of guide channels, the guide channels are diametrically opposite one another.

[00026] In an alternate embodiment, the guidance channels 20 extend in an arcuate path along the sides of the body portion, as shown by the dotted lines in FIG. 1C, and the interaction of the guidance fingers 22 with the guidance channels acts as a cam-and-follower mechanism to separate the endcap from the lancet body upon twisting of the endcap. In further alternate embodiments, the guidance finger(s) are provided on the lancet body and the guidance channel(s) are formed in the endcap, resulting in an inverse configuration but operating in a substantially similar manner to that described.

[00027] The user removes the endcap 16 by first twisting the endcap relative to the body portion 12, from a first angular position (FIG. 1A) to a second angular position (FIG. 1B). This twisting action preferably severs the connection between the endcap and an integrally molded body portion (if provided), and/or breaks the seal between the endcap and the tip element, thereby allowing easier endcap removal by reducing the

amount of pulling force required to remove the endcap. The user next pulls the endcap 16 axially away from the body portion 12 to complete the endcap removal (FIG. 1C). The guidance fingers 22 preferably remain engaged within the guidance channels 20 during the twisting step, and during the axial pulling step, until the endcap 16 releases from contact with the tip element 14, thereby resisting non-axial cocking or pivoting movement of the endcap during removal, which could bend or break the tip element.

[00028] The endcap 16 optionally also includes one or more gripping features to facilitate its removal. In the example embodiment shown in FIGS. 1A-1C, the gripping feature comprises a laterally extending wing or fin 30, which allows application of greater torque when twisting the cap, and which provides a larger gripping surface for axial pulling of the cap away from the body. The wing or fin 30 can be integrally molded with the remainder of the endcap, or can be a separate component attached to the remainder of the endcap. In example embodiments, the endcap and gripping features are intuitive for users, providing ergonomic and user-friendly operation.

[00029] The endcap 16 optionally also includes at least one indicator for distinguishing a used lancet from a new lancet. In the example embodiment shown in FIGS. 1A-1C, the indicator comprises the provision of a cap-replacement sleeve 40. The endcap 16 is replaced over the tip element 14 after use by placement of the cap-replacement sleeve 40 over the tip element, and into engagement with the body portion 12 of the lancet, to secure the endcap back in place over the tip element. The cap-replacement sleeve 40 is positioned on the endcap 10 at a location remote from the initial point of attachment of the endcap 16 to the body portion, so that a user can readily distinguish a used lancet from a new lancet. In a preferred embodiment, the endcap is replaced over the tip element of a used lancet in an orientation generally perpendicular to the endcap's initial orientation, to make it even easier to distinguish a used lancet from a new lancet.

[00030] In another embodiment shown in FIGS. 2A-2C, the lancet 110 is substantially as described above, and the endcap 116 comprises a large, easy to grip, generally U-shaped member. One or more guidance fingers 122 are preferably provided adjacent the interior free ends of the U-shaped endcap member, and are

releasably engaged within corresponding guidance channels 120 of the lancet body, to axially guide the endcap and prevent damage of the lancet tip 114 during endcap removal. The U-shaped member preferably has flat side surfaces that serve as gripping features, and can optionally be provided with ridges or knurling to assist the user in twisting and pulling the endcap. The endcap 116 preferably includes a cap-replacement sleeve portion 140, allowing the endcap to be replaced over the tip 114 after use, and serving as an indicator to distinguish a used lancet from a new lancet. The U-shaped member can be integrally molded with the cap-replacement sleeve portion 140, or can be a separate component attached thereto.

[00031] FIGURES 3A-3C show another embodiment of a lancet 210 according to the present invention. In this embodiment, interengaging threads 220 are formed on the end of the lancet body 212 adjacent the tip 214, and on the interior of a generally cylindrical endcap 216. The cap is twisted to disengage the threads and remove the endcap, and engagement of the threads as the cap is removed provides guidance to prevent non-axial cocking or pivoting movement of the endcap during removal, which could bend or break the tip element 214. The exterior of the endcap 216 provides an enlarged surface for gripping by the user during endcap removal, and is preferably is ridged or knurled. Misalignment of one or more indicia or surface features 250 on the endcap 216 and the lancet body 212, as seen in FIG. 3C, serves as an indicator to distinguish a used lancet from a new lancet.

[00032] Another embodiment of a lancet 310 according to the present invention is shown in FIGS. 4A-4D. The endcap 316 of this embodiment comprises a primary or inner cap portion 350 mounted within a secondary or outer cap portion 360. The inner surface of the open proximal end of the secondary or outer cap portion 360 preferably forms a close running or slight interference fit with the outer surface of the proximal end of the lancet body 312, and overlaps the lancet body a sufficient distance to provide guidance and prevent non-axial cocking or pivoting movement of the endcap during its removal. The outer surface of the secondary or outer cap portion 360 provides an enlarged gripping surface to assist in endcap removal. The primary or inner cap portion 350 preferably slides translationally within the secondary or outer cap portion 360,

between an axially retracted position (FIGS. 4A-4C) and an axially advanced position (FIG. 4d). Prior to use, the primary or inner cap portion 350, in its axially retracted position, encapsulates the tip portion 314 for safety and sterility. One or more stops 370 formed on the inner surface of the secondary or outer cap portion 360 abut the primary or inner cap portion 350 in its axially retracted position to limit its travel and prevent dislodgement during endcap removal. After use, the endcap is replaced over the tip portion, and contact with the tip portion 314 drives the primary or inner cap portion 350 into its axially advanced position within the secondary or outer cap portion 360. At least a window portion of the secondary or outer cap portion 360 is formed of a transparent or translucent material, or defines an opening or other indicia, to permit observation or indication of the primary or inner cap portion 350 moved into its axially advanced position, serving as an indicator to distinguish a used lancet from a new lancet.

[00033] FIGURES 5A-5C show another embodiment of a lancet 410 according to the present invention. The lancet body 412 preferably comprises one or more ribs or other surface features 413 adjacent its distal end, and the endcap 416 preferably includes a flared distal end 417, which combine to provide gripping features for easier endcap removal. Overlap of the proximal ends of the endcap and the lancet body provide guidance during endcap removal to prevent damage to the tip 414. The endcap 416 preferably includes a cylinder portion 480 and a piston portion 490 translationally mounted within the cylinder portion, and movable between an axially retracted position (FIGS. 5A-5B) and an axially advanced position (FIG. 5C). At least a portion of the piston 490 is exposed or visible through or beyond the cylinder 480, such that observation of the piston in its retracted position indicates a new lancet, and observation of the piston in its advanced position indicates a used lancet.

[00034] The invention also encompasses a lancing device incorporating at least one lancet as described herein. The lancing device of the present invention generally comprises at least one lancet, a housing, a drive mechanism such as a spring-biased piston assembly for propelling a lancet, and an actuation mechanism for charging

and/or releasing the drive mechanism. In alternate embodiments, the lancing device of the present invention is a single-use or a multi-use lancing device.

[00035] While the invention has been described with reference to several example embodiments, it will be understood by those skilled in the art that a variety of modifications, additions and deletions are within the scope of the invention, as defined by the following claims.

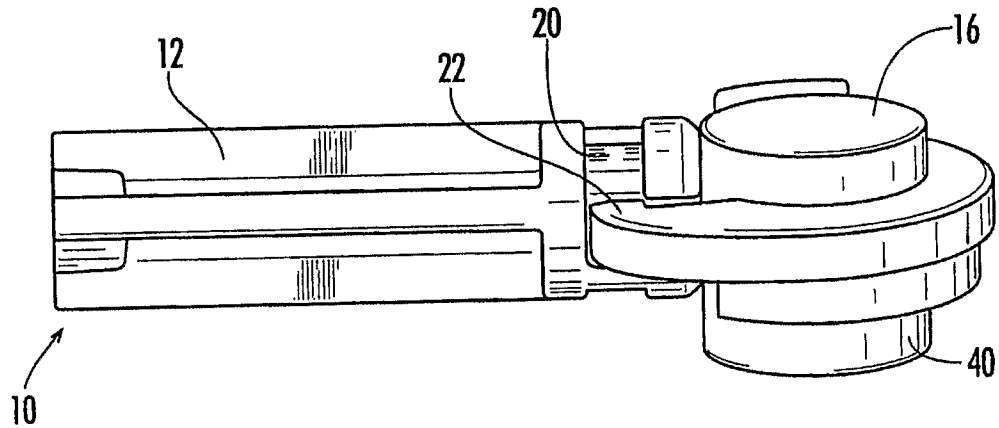
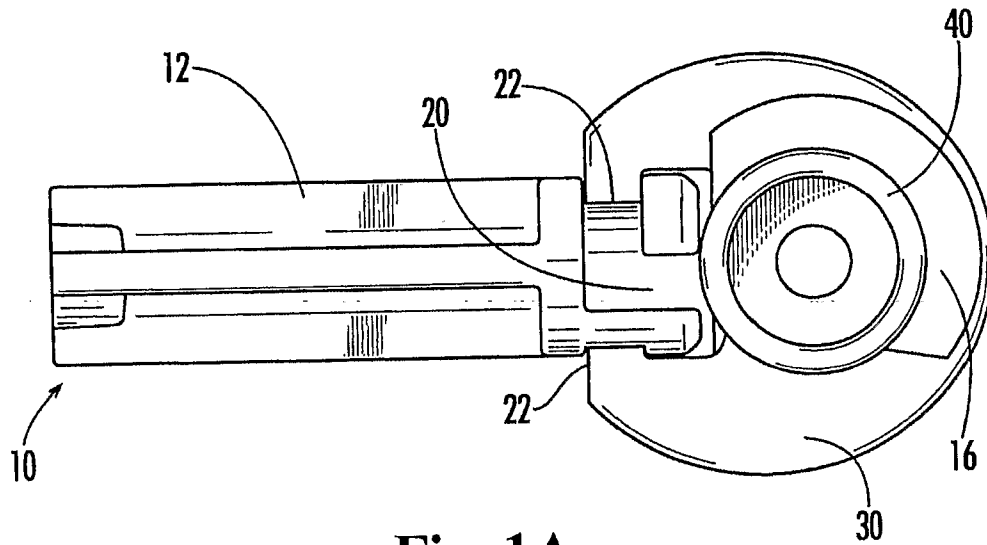
What is claimed is:

1. A lancet comprising a body portion, a sharp tip element extending in an axial direction from the body portion, and an endcap removably covering the tip element, wherein the endcap and the body portion comprise cooperating guidance features to maintain alignment of the endcap along a path in the axial direction and prevent damage to the tip element during removal of the endcap.
2. The lancet of Claim 1, wherein the sharp tip element comprises a 30-gauge or finer needle.
3. The lancet of Claim 1, wherein the cooperating guidance features comprise guidance channels along the body portion and cooperating guidance fingers on the endcap, wherein each guidance finger is releasably engaged within a corresponding guidance channel.
4. The lancet of Claim 3, wherein each guidance channel is generally L-shaped, having a first portion extending generally circumferentially on the lancet body, and a second portion extending generally axially from the first portion of the guidance channel to a proximal end of the lancet body.
5. The lancet of Claim 3, wherein each guidance channel extends in a generally arcuate path along the body portion.
6. The lancet of Claim 3, wherein the endcap comprises a generally U-shaped member having two free ends with confronting interior faces, and wherein the guidance fingers project from the interior faces proximal the free ends of the U-shaped member.
7. The lancet of Claim 1, wherein the cooperating guidance features comprise guidance fingers on the lancet body and guidance channels formed in the endcap.
8. The lancet of Claim 1, wherein the cooperating guidance features comprise interengaging threads on the lancet body and on the endcap.

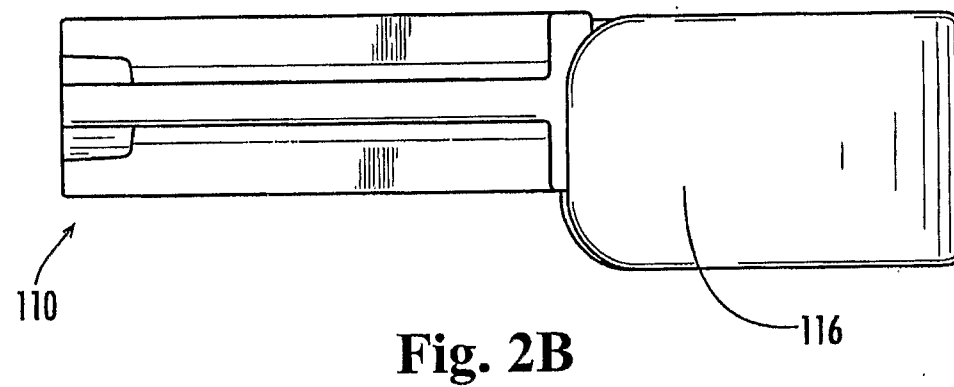
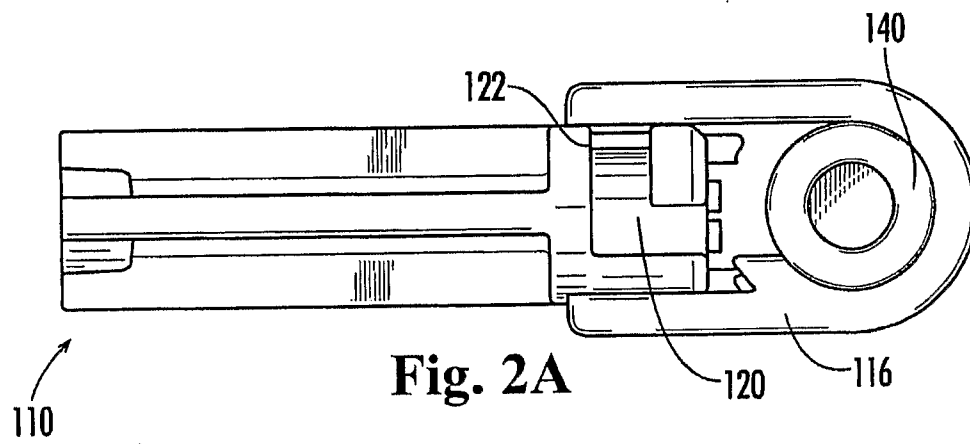
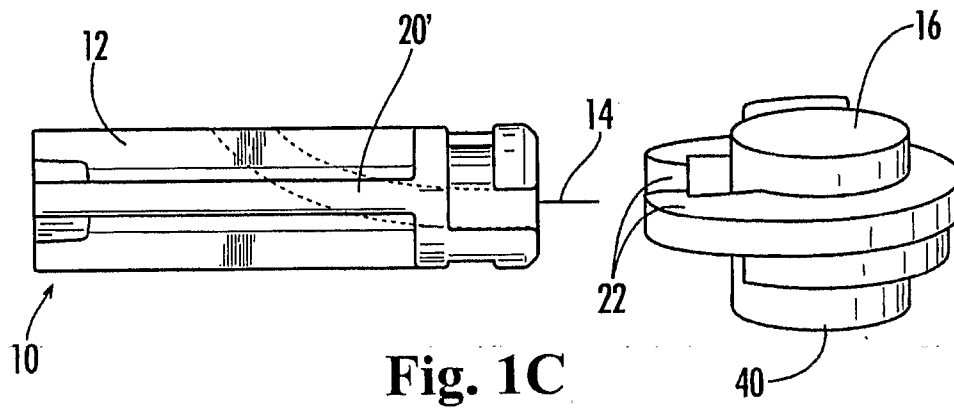
9. The lancet of Claim 1, wherein the cooperating guidance features comprise close-fitting overlapping surfaces of the endcap and the body portion, said overlapping surfaces extending generally parallel to one another a distance sufficient to prevent non-axial tilting of the endcap during removal.
10. The lancet of Claim 1, further comprising at least one indicator for distinguishing a used lancet from a new lancet.
11. The lancet of Claim 1, wherein the endcap comprises at least one gripping feature to facilitate removal.
12. A lancing device comprising at least one lancet according to Claim 1, and a drive mechanism coupled to the lancet.
13. A lancet comprising:
- a lancet body;
 - a sharp lancet tip projecting from the lancet body;
 - an endcap having an initial point of attachment for covering the sharp lancet tip when the endcap is attached to the lancet body in a first orientation, and being selectively removable from the lancet body to expose the sharp tip; and
 - an indicator for distinguishing a used lancet from a new lancet.
14. The lancet of Claim 13, wherein the indicator for distinguishing a used lancet from a new lancet comprises a cap-replacement sleeve portion of the endcap for covering the sharp lancet tip when the endcap is reattached to the lancet body in a second orientation, wherein the cap-replacement sleeve is remote from the initial point of attachment of the endcap.
15. The lancet of Claim 14, wherein the second orientation of the endcap is generally perpendicular to the first orientation of the endcap.

16. The lancet of Claim 13, wherein the endcap is threadedly attached to the lancet body, and wherein the indicator for distinguishing a used lancet from a new lancet comprises first indicia on the endcap and second indicia on the lancet body, wherein the first and second indicia are aligned in the first orientation of the endcap and misaligned when the endcap is reattached to the lancet body after removal.
17. The lancet of Claim 13, wherein the indicator for distinguishing a used lancet from a new lancet comprises a primary cap portion of the endcap and a secondary cap portion of the endcap, the primary cap portion being movable relative to the secondary cap portion from a first position into a second position when the endcap is reattached to the lancet body after removal.
18. The lancet of Claim 17, wherein at least a portion of the secondary cap portion is transparent to permit observation of the primary cap portion therethrough.
19. The lancet of Claim 13, wherein the indicator for distinguishing a used lancet from a new lancet comprises a cylinder portion of the endcap and a piston portion of the endcap, the piston portion being translationally mounted within the cylinder portion and movable between a first position indicating a new lancet and a second position indicating a used lancet.
20. The lancet of Claim 13, wherein the lancet tip projects from the lancet body in an axial direction, and wherein the endcap and the lancet body comprise cooperating guidance features to maintain alignment of the endcap along a path in the axial direction and prevent damage to the lancet tip during removal of the endcap.
21. The lancet of Claim 13, wherein the endcap comprises at least one gripping feature to facilitate removal.
22. A lancing device comprising at least one lancet according to Claim 13, and a drive mechanism coupled to the lancet.

23. A lancet comprising a lancet body, a sharp lancet tip projecting from the lancet body in an axial direction, and an endcap initially attached to the lancet body to cover the sharp lancet tip, the endcap being removable in the axial direction to expose the sharp lancet tip, and wherein the endcap comprises at least one gripping surface oriented in a direction generally perpendicular to the axial direction to facilitate removal of the endcap from the lancet body.
24. The lancet of Claim 23, wherein the at least one gripping surface comprises a laterally extending fin.
25. The lancet of Claim 23, wherein the at least one gripping surface comprises a flared distal end of the endcap.
26. The lancet of Claim 23, wherein the endcap is threadedly attached to the lancet body, and the at least one gripping surface comprises a plurality of ribs extending along the endcap.
27. The lancet of Claim 23, wherein the endcap is a generally U-shaped member, and the at least one gripping surface comprises a flat exterior face of the U-shaped member.
28. The lancet of Claim 23, wherein the endcap and the lancet body comprise cooperating guidance features to maintain alignment of the endcap along a path in the axial direction and prevent damage to the lancet tip during removal of the endcap.
29. The lancet of Claim 23, further comprising at least one indicator for distinguishing a used lancet from a new lancet.
30. A lancing device comprising at least one lancet according to Claim 23, and a drive mechanism coupled to the lancet.



SUBSTITUTE SHEET (RULE 26)



SUBSTITUTE SHEET (RULE 26)

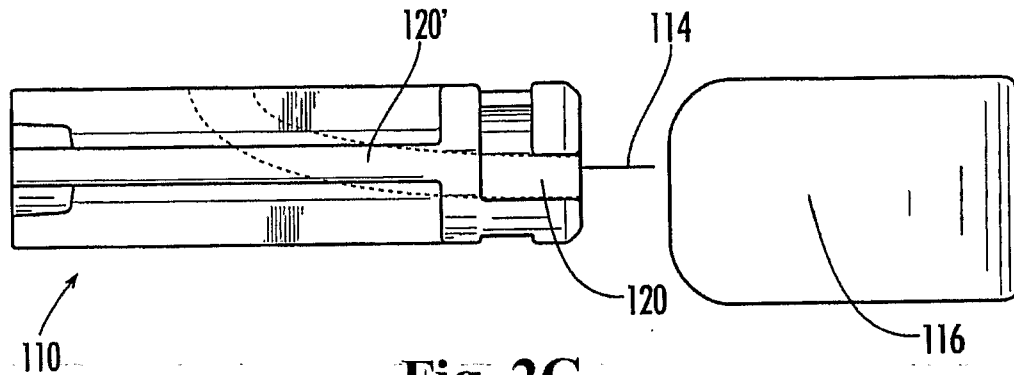


Fig. 2C

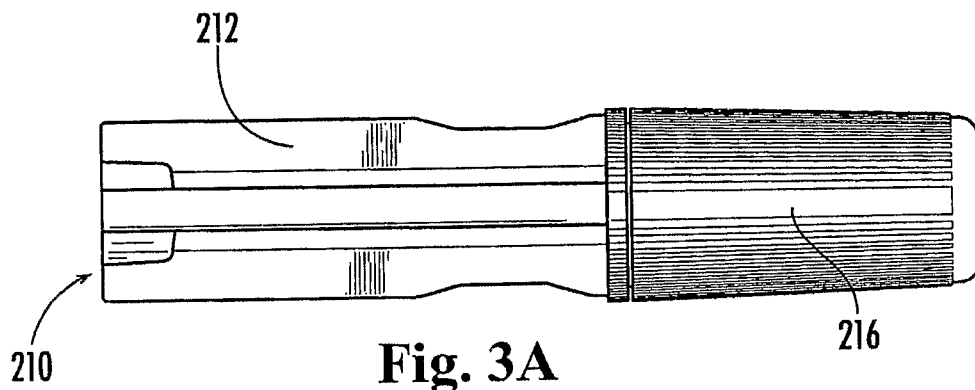


Fig. 3A

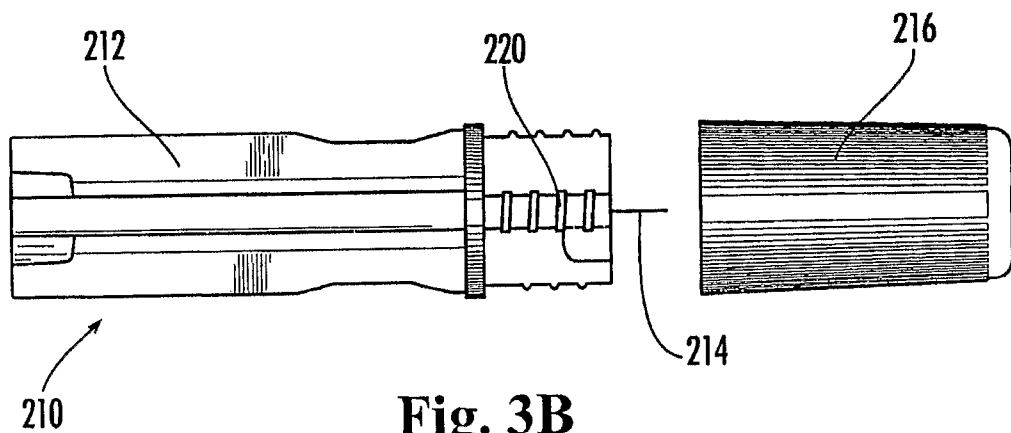
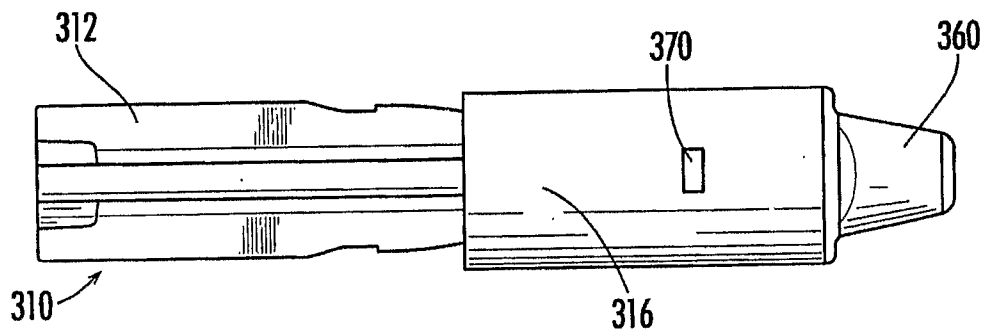
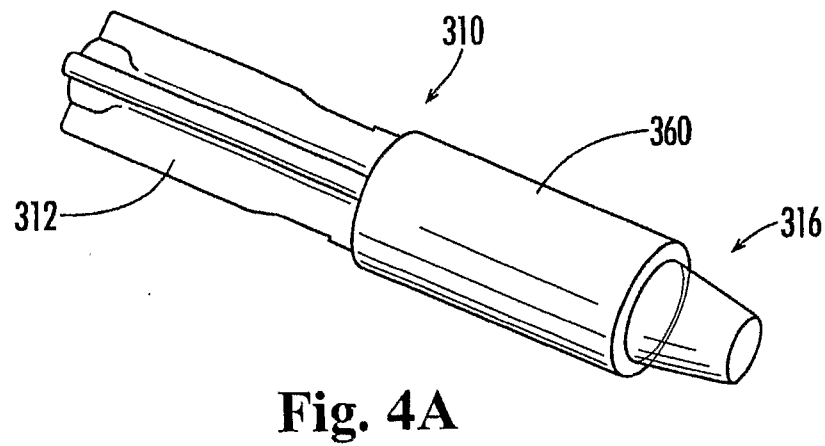
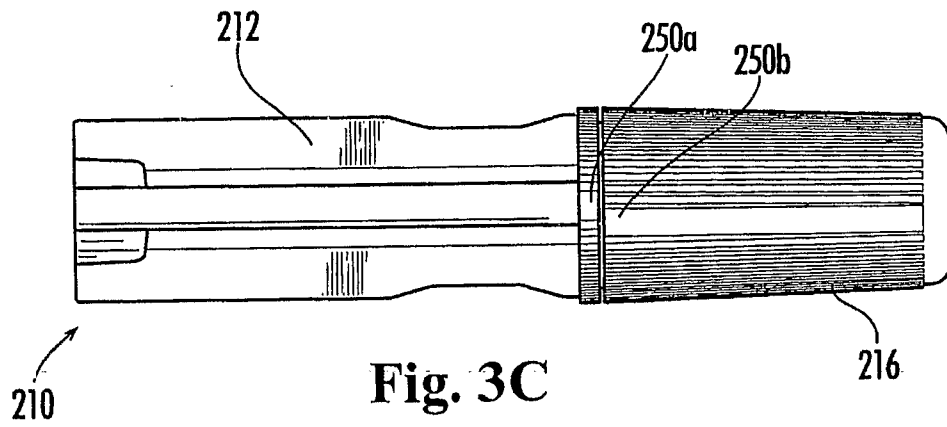
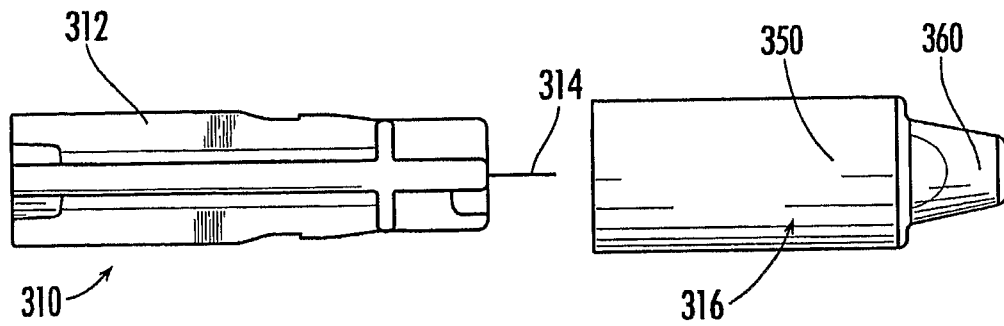
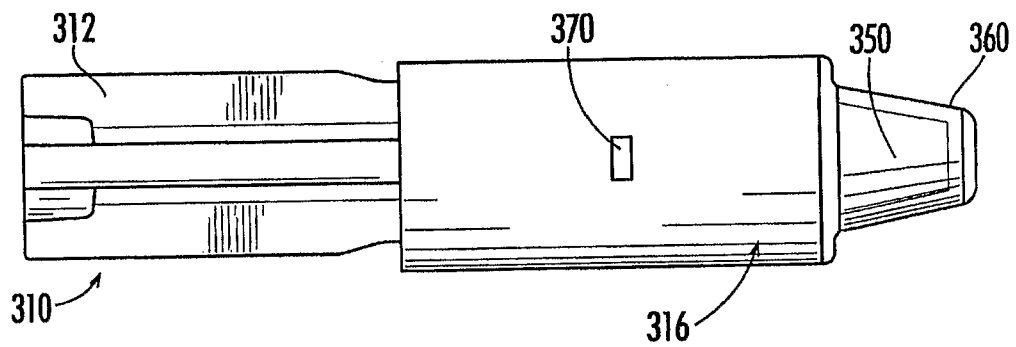
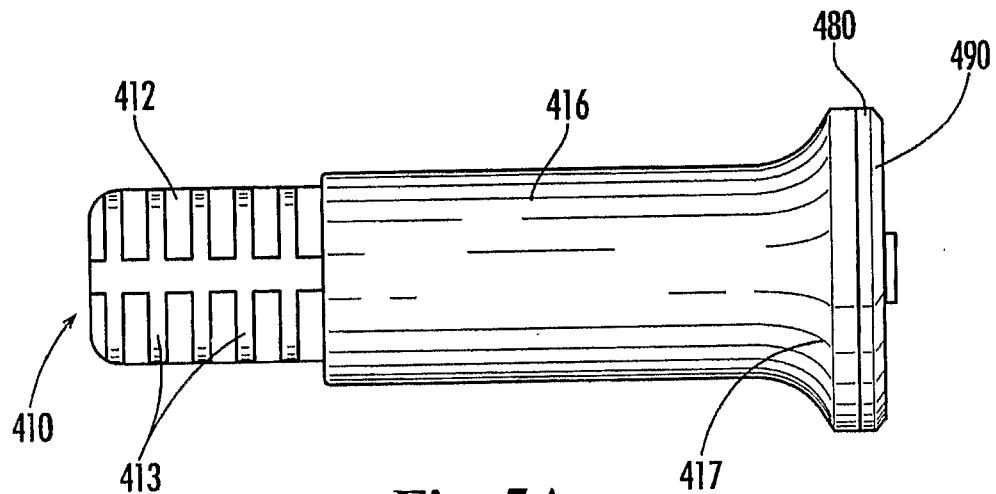
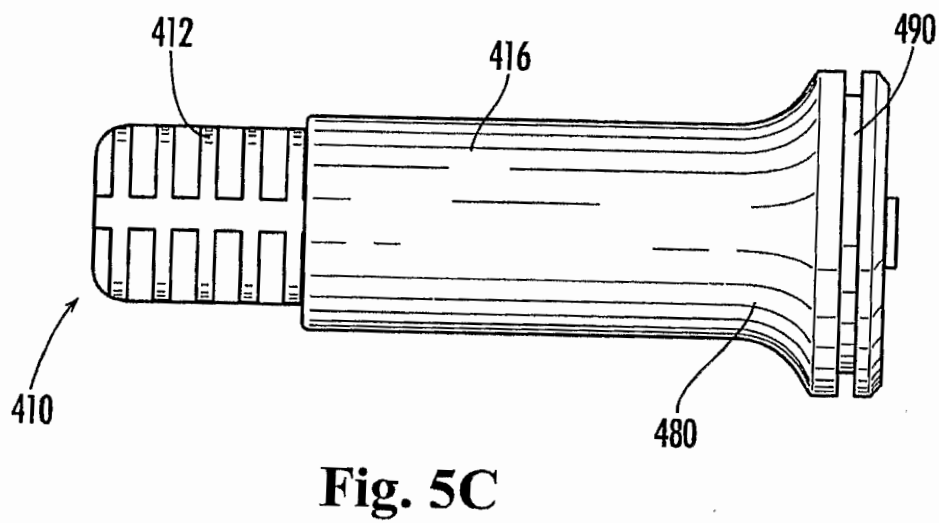
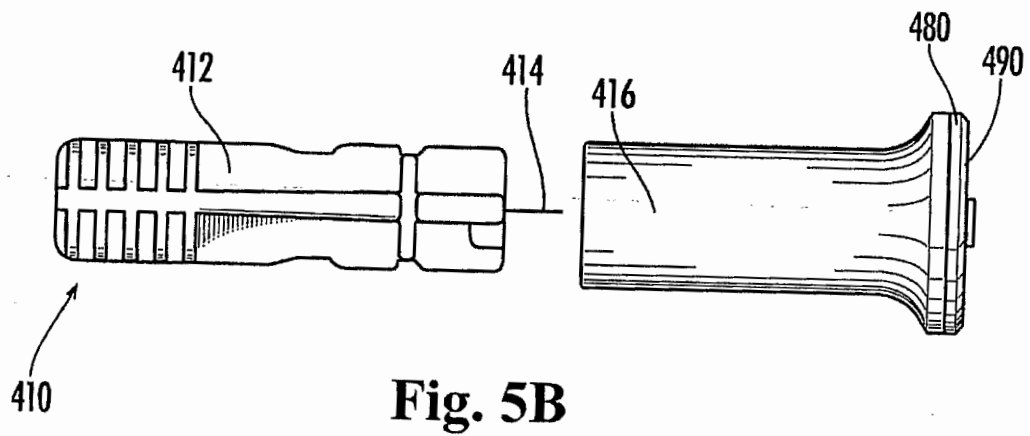


Fig. 3B



**Fig. 4C****Fig. 4D****Fig. 5A**

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