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(54) **Title:** LANCET DEVICE WITH DEPTH ADJUSTMENT AND LANCET REMOVAL SYSTEM AND METHOD

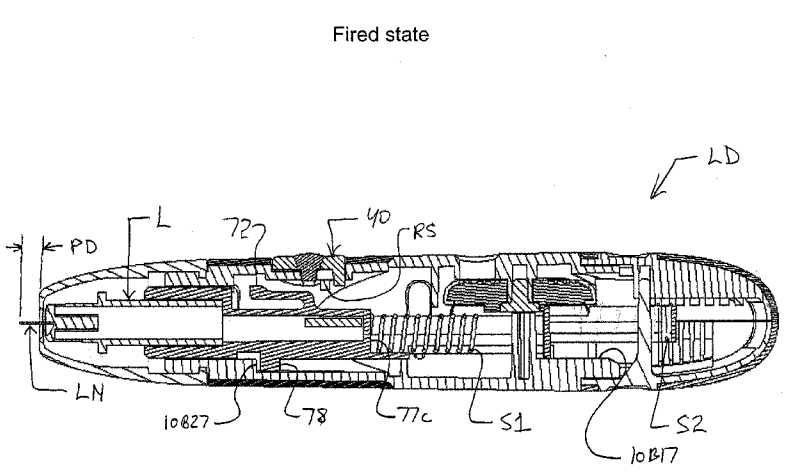

Fig. 4

(57) **Abstract:** Lancet device (LD) includes a housing (10), a removable front cap (20) mounted to the housing (10), a lancet holding member (70), and a trigger (40). A system (30) is utilized for placing the lancet device (LD) in a trigger-set or armed position (Fig. 3). A depth adjustment system includes a member (80) that is at least partially rotatably mounted and that has an axis of rotation arranged substantially perpendicular to a center axis of the lancet holding member (70). An ejection system (50) is utilized for at least one of preventing axial movement of the lancet holding member (70) and removing or ejecting a lancet (L) from the lancet holding member (70).

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LANCET DEVICE WITH DEPTH ADJUSTMENT AND A LANCET REMOVAL SYSTEM AND METHOD

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] The instant application is an International Application based on U.S. provisional application No. 60/929,252, filed June 19, 2007, the disclosure of which is hereby expressly incorporated by reference hereto in its entirety.

BACKGROUND OF THE INVENTION

1. Field of the Invention

[0002] The invention relates to a lancet device which utilizes depth adjustment and a lancet removal system. Lancet devices are used to penetrate and puncture the skin in order to allow the taking of a blood sample for testing. The present device allows the user to more safely remove and replace a lancet after each use.

2. Discussion of Background Information

[0003] Lancet devices are commonly used to prick the skin of the user so that one or more drops of blood may be extracted for testing. Some users, such as diabetics, for example, may have to test their blood sugar levels several times a day. This may be accomplished by the user using a simple needle. However, this procedure is often problematic for the user since the needle may be difficult to handle. Additionally, many users simply cannot perform the procedure owing to either a fear of needles or because they lack a steady hand. As a result, lancet devices have been developed which allow the user to more easily and reliably perform this procedure.

[0004] Most lancet devices lack convenient and flexible adjustability. Such devices are typically made adjustable by switching their tips. U.S. Patent No. Re. 32,922 to LEVIN et al. is one such device. That is, the user must remove one tip having a set depth and replace it with another having a different set depth. This, of course, creates the problem of storing the replaceable tips, which if not properly done, may result in their misplacement, damage, contamination, or the like. Typical lancet devices also require the user to handle the lancet during replacement and installation.

[0005] An improved device would allow the user to more easily adjust the depth of penetration and would overcome some of the disadvantages described above. Moreover, since the skin thickness can vary slightly from user to user and finger to finger, a need exists for efficiently adapting the depth of penetration. For example, an index finger may be more calloused than a middle finger, and the more calloused finger will typically have thicker skin. By adjusting the depth of puncture so that the depth is no greater than necessary for extracting a required amount of blood, any pain experienced by the user may be minimized. The present device allows the user to more safely remove and replace a lancet after each use.

[0006] What is needed is a lancet device which can accurately and precisely control the depth of penetration of the needle relative to the surface of the user's skin while also being easy to use. It is also desirable for the user to be able to use and adjust the depth penetrating setting with just one hand and/or with less effort that currently required with existing lancet devices. What is also needed is a lancet device which does not require the user to handle the lancets so as to prevent inadvertent pricking of the user's skin.

SUMMARY OF THE INVENTION

[0007] According to one illustrative aspect of the invention there is provided a lancet device comprising a housing, a removable front cap mounted to the housing, a lancet holding member, a trigger, a system for placing the lancet device in a trigger-set or armed position, a depth adjustment system comprising a member that is at least partially rotatably mounted and that has an axis of rotation arranged substantially perpendicular to a center axis of the lancet holding member, and an ejection system for at least one of preventing axial movement of the lancet holding member and removing or ejecting a lancet from the lancet holding member.

[0008] The ejection system may comprise a manually activated slide button. The ejection system may each of prevent axial movement of the lancet holding member and remove or ejects the lancet from the lancet holding member.

[0009] The member that is at least partially rotatably mounted may comprise a thumbwheel having plural cam or stop surfaces. The member that is at least partially rotatably mounted may comprise a thumbwheel having indicia. The member that is at least partially rotatably mounted may comprise a thumbwheel having indicia which is visible through an opening located in the housing. The member that is at least partially rotatably mounted may comprise a thumbwheel having portions which can be gripped by a user from outside of the housing. The member that is at least partially rotatably mounted may comprise a thumbwheel having oppositely arranged portions which project outside of the housing.

[0010] The lancet device may further comprise a first spring for causing movement of the lancet holding member towards a puncturing position and a second for causing a back cap to move towards an initial position from a retracted position. The lancet device may further comprise a first spring for causing movement of the lancet holding member towards a puncturing position, a second for causing a back cap to move towards an initial position from a retracted position, and a third spring for causing a slide member of the ejection system to move towards an initial position from an extended position.

[0011] The invention also provides for a method of puncturing a surface of skin using the lancet device of the type described above, wherein the method comprises arranging the lancet device

adjacent against a user's skin and triggering the lancet device so that a lancet is caused to penetrate the user's skin.

[0012] The invention also provides for a lancet device comprising a housing, a removable front cap mounted to the housing, a lancet holding member having a front end adapted to receive therein a removable lancet, a trigger, a system for placing the lancet device in a trigger-set or armed position, a depth adjustment system comprising a member having plural cam surfaces, and an ejection system for at least one of preventing axial movement of the lancet holding member, removing or ejecting a lancet from the lancet holding member, and removing or ejecting the front cap.

[0013] The ejection system may comprise a manually activated slide button. The ejection system may each of prevent axial movement of the lancet holding member, remove or eject the lancet from the lancet holding member, and remove or eject the front cap.

[0014] The member may be at least partially rotatably mounted and comprises a thumbwheel. The thumbwheel may comprise indicia. The indicia may be visible through an opening located in the housing. The thumbwheel may be one of has portions which can be gripped by a user from outside of the housing, and oppositely arranged portions which project outside of the housing.

[0015] The lancet device may further comprise a first spring for causing movement of the lancet holding member towards a puncturing position and a second for causing a back cap to move towards an initial position from a retracted position. The lancet device may further comprise a first spring for causing movement of the lancet holding member towards a puncturing position, a second for causing a back cap to move towards an initial position from a retracted position, and a third spring for causing a slide member of the ejection system to move towards an initial position from an extended position.

[0016] The invention also provides for a method of puncturing a surface of skin using the lancet device of the type described above, wherein the method comprises arranging the lancet device adjacent against a user's skin and triggering the lancet device so that a lancet is caused to penetrate the user's skin.

[0017] The invention also provides for a lancet device comprising a housing having an ergonomic shape, a removable front cap mounted to the housing, a movably mounted lancet holding member having a front end adapted to receive therein a removable lancet, a trigger arranged on a side wall of the hosing, a system for placing the lancet device in a trigger-set or armed position, a depth adjustment system comprising a member having plural cam surfaces, and an ejection system for at least one of preventing axial movement of the lancet holding member, removing or ejecting a lancet from the lancet holding member, and removing or ejecting the front cap.

[0018] The invention also provides for a lancet device of the type disclosed herein whose parts utilize the same materials as the materials of corresponding parts of US 10/441,065 to SCHRAGA filed May 20, 2003, the disclosure of this document is hereby expressly incorporated by reference in its entirety.

[0019] Other exemplary embodiments and advantages of the present invention may be ascertained by reviewing the present disclosure and the accompanying drawing.

BRIEF DESCRIPTION OF THE DRAWINGS

[0020] The present invention is further described in the detailed description which follows, in reference to the noted plurality of drawings by way of non-limiting examples of exemplary embodiments of the present invention, in which like reference numerals represent similar parts throughout the several views of the drawings, and wherein:

Fig. 1 shows a left front side perspective view of a non-limiting embodiment of the invention;

Fig. 2 shows a side cross-section view of Fig. 1. The device is shown in an initial or intermediate state;

Fig. 3 shows a side cross-section view of Fig. 2 after the device is placed in an arming or trigger-set position;

Fig. 4 shows a side cross-section view of Fig. 2. The device is shown in a triggered state and before the lancet holding member is automatically moved back to the position shown in Fig. 2;

Figs. 5 and 6 show an enlarged partial views of a front portion of the lancet device shown in Fig. 1 with the front cap being represented as transparent;

Fig. 7 shows a partial view of a front portion of the device of Fig. 1 with the front cap removed and after the lancet ejection system has been moved to a lancet ejection position;

Fig. 8 shows a cross-section view of the front portion shown in Fig. 7 after the lancet ejection system has been allowed to move to an initial position;

Fig. 9 shows a cross-section view of the front portion shown in Fig. 7;

Fig. 10 shows a bottom partial view of a front portion (bottom housing part removed) of the device of Fig. 1 with the front cap removed and after the lancet ejection system has been moved to a lancet ejection position;

Fig. 11 shows a top partial view of a front portion (top housing part and lancet holding member removed) of the device of Fig. 1 with the front cap removed and after the lancet ejection system has been moved to a lancet ejection position;

Fig. 12 shows a top partial view of a middle portion (top housing part and lancet holding member removed) of the device of Fig. 1 with the lancet ejection system in an initial position;

Fig. 13 shows an enlarged side cross-section view of a middle portion of the lancet device of Fig. 2 and illustrates the depth adjustment system;

Fig. 14 shows an enlarged side cross-section view of a middle portion of the lancet device of Fig. 4 and illustrates the depth adjustment system;

Fig. 15 shows a bottom side perspective view of the thumbwheel used in the lancet device of Figs. 13 and 14;

Fig. 16 shows an enlarged cross-section view of a rear portion of the lancet device of Fig. 3 and illustrates how the user can grip the back cap;

Fig. 17 shows the enlarged cross-section view of Fig. 16 and illustrates how the user can move the back cap to a trigger-set position so as to place the lancet device in the armed position of Fig. 3 and 16;

Figs. 18 and 19 show a front portion of the lancet device of Fig. 1 and shows how a user can see a visible indicator of when the lancet device is in an armed position;

Fig. 20 shows a perspective top side view of the upper or right-side housing part used in the two-piece housing of the lancet device shown in Fig. 1;

Fig. 21 shows a perspective outside view of the upper housing part shown in Fig. 20;

Fig. 22 shows a perspective inside view of the upper housing part shown in Figs. 21;

Fig. 23 shows a perspective bottom side view of the lower or left-side housing part used in the two-piece housing of the lancet device shown in Fig. 1;

Fig. 24 shows a perspective inside view of the lower housing part shown in Fig. 23;

Fig. 25 shows a perspective outside view of the lower housing part shown in Figs. 23;

Fig. 26 shows a perspective inside view of the front cap used in the lancet device shown in Fig. 1;

Fig. 27 shows a perspective outside view of the front cap shown in Fig. 26;

Fig. 28 shows a perspective rear side view of an upper portion of the back cap used in the lancet device shown in Fig. 1;

Fig. 29 shows an enlarged perspective rear side view of an upper portion of the back cap used in the lancet device shown in Fig. 1;

Fig. 30 shows a perspective inside view of the upper portion of the back cap shown in Fig. 29;

Fig. 31 shows a perspective rear side view of a lower portion of the back cap used in the lancet device shown in Fig. 1;

Fig. 32 shows an enlarged perspective rear side view of a lower portion of the back cap used in the lancet device shown in Fig. 1;

Fig. 33 shows a perspective inside view of the lower portion of the back cap shown in Fig. 32;

Fig. 34 shows a perspective front side view of the thumb wheel used in the embodiment of Fig. 1;

Fig. 35 shows an enlarged view of Fig. 34;

Fig. 36 shows a perspective rear side view of the thumb wheel shown in Fig. 35;

Fig. 37 shows a perspective front side view of the trigger used in the embodiment of Fig. 1;

Fig. 38 shows an enlarged view of Fig. 37;

Fig. 39 shows a perspective rear side view of the trigger shown in Fig. 38;

Fig. 40 shows a bottom side perspective view of the lancet ejection member used in the lancet device shown in Fig. 1;

Fig. 41 shows a top side perspective view of the lancet ejection member shown in Fig. 40;

Fig. 42 shows a top perspective view of the lancet holding member used in the lancet device shown in Fig. 1;

Fig. 43 shows a top left-side perspective view of Fig. 42;

Fig. 44 shows a bottom right-side perspective rear side view of Fig. 43;

Fig. 45 shows a perspective side view of the lancet holding member/back cap return spring used on the lancet device of Fig. 1;

Fig. 46 shows a perspective side view of the drive spring which causes the lancet holding member to move to the puncturing position of the lancet device shown in Fig. 1;

Fig. 47 shows a perspective side view of the spring used to bias the lancet ejection system of the lancet device shown in Fig. 1;

Fig. 48 shows a top perspective view of the locking member used in the lancet device shown in Fig. 1; and

Fig. 49 shows a bottom perspective view of the locking member shown in Fig. 48.

DETAILED DESCRIPTION OF THE PRESENT INVENTION

[0021] The particulars shown herein are by way of example and for purposes of illustrative discussion of the embodiments of the present invention only and are presented in the cause of providing what is believed to be the most useful and readily understood description of the principles and conceptual aspects of the present invention. In this regard, no attempt is made to show structural details of the present invention in more detail than is necessary for the fundamental understanding of

the present invention, the description taken with the drawings making apparent to those skilled in the art how the several forms of the present invention may be embodied in practice.

[0022] Figs. 1-49 show one non-limiting embodiment of a lancet device **LD**. The lancet device **LD** includes the following main components: a housing or body **10** which preferably comprises housing parts **10A** and **10B**, a front cap **20**, a back cap **30** which preferably comprises parts **30A** and **30B**, a trigger **40**, a lancet advance button or member **50**, a locking member **60**, a lancet holding member **70**, a depth adjustment or thumb wheel member **80**, and three springs **S1**, **S2** and **S3**.

[0023] As can be seen in Fig. 1, the lancet device **LD** can preferably have, by way of non-limiting example, an overall length **OL** which is approximately 5 inches and an overall width or diameter (measured over the device's largest portion) of approximately 1.25 inches. The lancet device **LD** also preferably has an ergonomic shape such that it can be held comfortably in a user's hand such that the user can rotate (both clockwise and counterclockwise) the depth adjustment thumb wheel **80** with the user's thumb and index finger, as will be described in detail later on, to set the depth of penetration prior to use. The user can also depress and slide forward the advance button **50** in order cause a forward advance of a lancet and optionally simultaneously cause removal of the front cap **20**, as will be described in detail later on. The user can also depress the trigger **40** with either the user's thumb of index finger. The only step which likely requires the user to use two hands, is the step of placing the lancet device **LD** is an armed or trigger-set position – which will be described in detail later on.

[0024] As can be seen in Figs. 2-4, the lancet device **LD** functions as follows: In the position shown in Fig. 2, the lancet device **LD** is shown in the static or initial position. This is the preferred position that the device would assume during shipping, storage, and after the device is triggered or fired. In this position, the drive spring **S1** is in a relaxed or non-compressed or expanded position. The back or arming spring **S2** is in a slightly compressed state so as to apply a biasing force that forces the back cap **30** to a forward-most position. The advance button **50** and the trigger **40** are also in an initial position. The slide spring **S3** (not visible in Fig. 2) is in a slightly compressed state so as to apply a biasing force that forces the ejection slide member **50** to a rearward-most position.

[0025] In the position shown in Fig. 3, the lancet device **LD** is shown in the loading, armed or trigger-set position. This is the position which arms the lancet device and occurs when the user moves the back cap **30** rearward to cause the deflecting member **72** to become releasably locked to the retaining shoulder **RS**. In this position, the spring **S1** is in a compressed state or position. Spring **S2** is in an almost relaxed or a more expanded state or position, but is still able to bias the back cap **30** toward an initial position. The arming or armed position shown in Fig. 3 can take place when the

user grips the back cap **30** with one hand and the body **10** with the other hand and pulls the back cap **30** away from the body **10**, and then lets go of the back cap **30**.

[0026] In the position shown in Fig. 4, the lancet device **LD** is shown in the firing or fired position. This is the position in which a user depresses the trigger **40** so as to cause the member **72** to deflect inwardly and release from the shoulder **RS**. This releases the energy stored in the spring **S1** and causes the lancet holding member **70** to move forwardly, which automatically causes the lancet **L** to project out of the front surface of the front cap **20** and cause a puncture in a user's skin. Of course, the position shown in Fig. 4 merely shows a snap-shot of the lancet needle **LN** in the extended or puncturing position, i.e., defined by the puncturing depth **PD**. In actuality, the lancet needle **LN** would move from the position in Fig. 3 (fully retracted or trigger-set position) to that of Fig. 4 (fully extended or puncturing position), and then finally to that of Fig. 2 (initial position) in a fraction of a second. In the firing position, the spring **S1** is in a substantially fully expanded position owing to the forward movement of the member **70** as caused by the rapid axial expansion of the spring **S1** acting on the flange of surface **77c** of member **70**. After the member **70** moves to a maximum forward position shown in Fig. 4, as determined by contact between a free end of the lancet **L** and an inner surface of the front cap **20** and/or by contact between the projection **78** and projection **10B27**, the spring **S2**, which has substantially reached a maximum amount of allowable compression, will expand axially back to an original position, which, in turn, places the lancet device **LD** back in the position shown in Fig. 2. At this point, the user has the option of activating the lancet advancing system **LES** (see Figs. 7-9) in order to cause removal of the front cap **20** and to allow for removal of the used lancet **L** so that the next or a fresh lancet can be placed on the lancet holding member **70**.

[0027] With reference to Figs. 5 and 6, it can be seen that the lancet device **LD** includes a removable front cap **20** which covers a front area of the lancet device **LD** that includes a front end of the lancet holding member **70** and a lancet **L**. The lancet **L** is axially retained inside an elongated cylindrical opening **LRO** (see Fig. 44) of the lancet holding member **70** by deflectable portions of the front end portion **71a** which engages with an outer cylindrical surface of the lancet **L**. Thus, when the lancet holding member **70** moves axially within housing **10**, the lancet **L** moves along therewith. As is apparent from Figs. 5 and 6, the front cap **20** can be removably secured to the housing **10** via engagement between oppositely arranged projections **27** and grooves **G** formed in housing parts **10A** and **10B**. Other types of connections can be utilized such as a snap connection of the type disclosed in US Patent Nos. 5,908,434 to SCHRAGA and 6,530,937 to SCHRAGA. The disclosure of each of these documents is hereby expressly incorporated by reference in its entirety. In order to remove the front cap **20**, the user can either rotate the front cap **20** relative to the housing

10 (by e.g., about 90 degrees) to cause the projections **27** to align with oppositely arranged axial slots **AL** and then simply pull the front cap **20** away from the housing **10** or the user can move the slide member **50** forward (see Figs. 7 and 9) to cause the end **53** to move into engagement with end **21** of the front cap **20** and thereby cause the projections **27** to come out of snap engagement with the grooves **G**.

[0028] The details of the lancet ejecting system **LES** will now be described with reference to Figs. 7-12. Fig. 8 shows the system **LES** in an initial position. In this position, the slide member **50** has a button portion **51** abutting or substantially near surfaces **10A14** and **10B14** (see Figs. 22 and 24). Figs. 7 and 9 show the system **LES** in a final or activated position. In this position, the slide member **50** has a button portion **51** abutting or substantially near surfaces **10A15** and **10B15** (see Figs. 22 and 24). A spring **S3** is arranged in a retaining groove **10B26** and applies a biasing force against surface **10B20a** and a surface of member **54** (see Fig. 12). In operation, the advance button **50** is slid forward from the position shown in Fig. 8 to the position shown in Figs. 7 and 9. This causes compression of the spring **S3** and causes the lancet engaging member **55** (which extends into the holding member **70** via the elongated slot **79**) to engage or contact a rear end of lancet **L**. However, when the slide member **50** is slid forward slightly against the biasing force of spring **S3**, this initial forward movement of the slide member **50** automatically causes the locking member **60** to pivot about axle projection **10B10** so that projection **65** engages with shoulder **78** (see Fig. 10) of the lancet holding member **70**. This pivoting movement of the locking member **60** occurs as a result of sliding interaction between the guide projection **64** and the guide groove **57**. Continued forward sliding movement of the slide member **50** causes the lancet L to move or advance forwards (until finally ejected) while the lancet holding member **70** is axially retained by the locking member **60**. This forward movement of the slide member **50** maintains the locking member **60** in the locking position because of continued engagement between the guide projection **64** and the guide slot **57**. Although not shown in Figs. 7-12, the end **53** also moves with button **51** and would cause the front cap **20** to be removed along with the lancet **L**. This causes the front cap **20** to be ejected and allows the user to install a fresh or new lancet **L**. The user can then release the advance button **50** (which will be automatically retracted by the spring **S3**) and re-install the front cap **20** in order to place the device **LD** back into an initial or intermediate position shown in Fig. 2.

[0029] With reference to Figs. 13-15 it can be seen that the user can set a depth of penetration of the lancet device **LD** before the device is triggered and/or after the device is triggered. This can occur by the user rotating the thumb wheel **80** in either clockwise or counterclockwise directions. Such rotational movement determines the maximum forward position of the lancet

holding member **70** and specifically projection **74**. This position of the projection **74** (which contacts one of the stop surfaces **86a-86f**) also determines the amount of forward axial movement of the lancet holding member **70** as discussed above. This movement changes as a result of the rotational position of the surfaces **86a – 86f** of the thumb wheel **80** relative to the projection **74**, such that when stop surface **86a** of the thumb wheel **80** is contacted by projection **74**, the holding member **70** moves axially forward by a greater amount (producing a deeper puncture) than when stop surface **86f** of the thumb wheel **80** is contacted by projection **74** producing a shallower puncture). The user can distinguish which stop surface **86a – 86f** is located in a position to be contacted by projection **74** by viewing the corresponding indicia **88** (see Figs. 34-36) through the window or opening **10A13** in the housing **10** (see Fig. 14).

[0030] Figs. 16 and 17 show how the lancet device **LD** can be armed or placed in the trigger-set position of Fig. 3. This is the position which arms the lancet device and occurs when the user moves the back cap **30** rearward to cause the deflecting member **72** to become releasably locked to the retaining shoulder **RS** (see Fig. 3). During this movement, the spring **S2** is compressed. However, when the user releases his or her grip from the back cap **30**, the spring **S2** automatically causes the back cap **30** to move toward an initial position shown in Fig. 16. The user can grip the indentations **30A4** and **30B4** of the back cap **30** with one hand and the body **10** with the other hand and pull the back cap **30** away from the body **10**, and then let go of the back cap **30**.

[0031] Figs. 18 and 19 show how the lancet device **LD** can provide a indication to the user that the device is armed or placed in the trigger-set position of Fig. 3, thereby providing a safety feature. By way of non-limiting example, the trigger **40** includes an opening or transparent window **46** (see Fig. 38) which allows a user to see inside the device. As such, when the lancet holding member **70** is positioned in the position shown in Fig. 3, the indicator **73** (in the form of, e.g., a red dot) can be visible through the window **46** (see Fig. 43), thereby providing a visual indicator to the user of the armed position. Of course, when the lancet holding member **70** is in the position shown in Fig. 2, the indicator **73** (in the form of, e.g., a red dot) is not visible through the window **46**, thereby providing a visual indicator to the user of the unarmed position.

[0032] The details of the parts utilized in the lancet device **LD** shown in Figs. 1-4 will now be described with reference to Figs. 20-49.

[0033] With reference to Figs. 20-22, it can be seen that the upper housing part **10A** includes a front end **10A1** having a partially cylindrical inner surface **10A4** and a partially cylindrical outer surface **10A3** which serves as a mounting area for the front cap **20** as well as a rear end **10A2**. A generally helical groove **G** is arranged on the surface **10A3** of the housing part **10A** and is configured

to receive therein one of the projections **27** of the front cap **20**. The semi-cylindrical portion **10A3** which (together with semi-cylindrical portion **10B3**) is sized and configured to slidably and rotatably receive thereon the rear end of the front cap **20**. The housing part **10A** also has a main body portion **10A5** which is preferably ergonomically shaped. Oppositely arranged integrally formed projections **10A6** each extend or projects inwardly from the body portion **10A5** and includes a mounting opening which is sized and configured to receive therein one of the mounting projections **10B6**. Oppositely arranged integrally formed projections **10A7** each extend or projects inwardly from the body portion **10A5** and includes a mounting opening which is sized and configured to receive therein one of the mounting projections **10B7**. Oppositely arranged integrally formed projections **10A8** each extend or projects inwardly from the body portion **10A5** and includes a mounting opening which is sized and configured to receive therein one of the mounting projections **10B8**. A centrally arranged mounting projection **10A9** extends inwardly from the body portion **10A5** and is sized to allow the thumbwheel **80** to be rotatably mounted thereto. Projections **10A24** are configured to function as a bearing surface for the surface **81** of the thumbwheel **80**. A trigger opening **10A10** is formed in the body portion **10A5** and is sized and configured to receive therein the projecting portions **43a** and **43b** of the trigger **40** (see Figs. 37-39). Once inserted in the opening **10A10**, the projecting portions **43a** and **43b** of the trigger **40** prevent removal of the trigger **40** from the housing part **10A**, but allow the trigger **40** to move against the biasing force of an integrally formed deflecting member **10A11** which functions as a flat spring and bias the trigger **40** towards an extended or initial position. The deflectable member **10A11** is deflected by contact with projection **44** of the trigger **40** when the trigger **40** is depressed. A retaining shoulder **RS** is formed in the body portion **10A5** and is configured to releasably engage and/or lock with a deflecting portion **72** of the lancet holding member **70** (see Figs. 42-44). Oppositely arranged indented sections **10A12** are arranged in an area of the middle rear end of the housing part **10A** and together with indented section **10B12** form an area for the user to activate the thumbwheel **80**. A viewing opening **10A13** is arranged in the body portion **10A5** of the front end of the housing part **10A**, which allows a user to view indicia **88** of the thumbwheel **80** when the thumbwheel **80** is mounted to the projection **10A9**. A half-slot or half-groove defined by surfaces **10A14** and **10A15** (together with half-groove formed by surfaces **10B14** and **10B15**) forms a guide groove which guides the sliding movement of the slide member **50** between an initial and final position (see Figs. 8 and 9). The slide member **50** contacts and/or substantially abuts stop surface **10A14** in the initial position shown in Fig. 8 (as a result of the biasing force of the spring **S3**) and contacts and/or substantially abuts stop surface **10A15** in the final position shown in Fig. 9 (as a result of the user causing compression of the spring **S3**). Oppositely

arranged reinforcing ribs **10A16** are also utilized. A projection **10A17** is utilized to abut projection **10B14** and prevent axial movement of the ring portion **61** of the locking member **60**. A rear portion of the housing part **10A** includes surface **10A19** which is configured to abut with surface **10B19** of the housing part **10B**, and a groove **10A22** which slidably receives therein projection **30A6**. Housing part **10A** also includes reinforcing projections **10A20** and **10A21**. The rear portion of the housing part **10A** also includes surface **10A23** which is configured to be slidably engaged by the inner surface of portion **30A1** as well as oppositely arranged guide surfaces **10A25** which are sized and configured to be slidably engaged by the inner surfaces of members **30A3**. The guide surfaces **10A25** extend into openings in the member **10A** so as to form slots **10A25a** (see Fig. 22). As is apparent from Figs. 20-22, the housing part **10A** can preferably be a one-piece member and is most preferably a one-piece synthetic resin member. Of course, the member **10A** can also be an assembly of plural components provided it functions in a manner similar to that of the member shown in Figs. 20-22.

[0034] With reference to Figs. 23-25, it can be seen that the lower housing part **10B** includes a front end **10B1** having a partially cylindrical inner surface **10B4** and a partially cylindrical outer surface **10B3** which serves as a mounting area for the front cap **20** as well as a rear end **10B2**. A generally helical groove **G** is arranged on the surface **10B3** of the housing part **10B** and is configured to receive therein one of the projections **27** of the front cap **20**. The semi-cylindrical portion **10B3** which (together with semi-cylindrical portion **10A3**) is sized and configured to slidably and rotatably receive thereon the rear end of the front cap **20**. The housing part **10B** also has a main body portion **10B5** which is preferably ergonomically shaped. Oppositely arranged integrally formed projections **10B6** each extend or projects inwardly from the body portion **10B5** and is sized and configured to extend into the opening of mounting projections **10A6**. Oppositely arranged integrally formed projections **10B7** each extend or projects inwardly from the body portion **10B5** and is sized and configured to extend into the openings in the mounting projections **10A7**. Oppositely arranged integrally formed projections **10B8** each extend or projects inwardly from the body portion **10B5** and are sized and configured to extend into the mounting openings of the mounting projections **10A8**. A centrally arranged D-shaped guide projection **10B9** extends inwardly from the body portion **10B5** and has an upper surface **10B24** configured to abut surface **87** of the thumbwheel **80**. The projection **10B9** also extends through the slot **77b** and into the space **77a** of the holding member **70**, and participates in guiding the axial movement of the holding member **70**. A guide surface arrangement **10B11** is formed in the body portion **10B5** and is configured to support and allow for the sliding and/or pivoting movement of the locking member **60** (see Fig. 11). Oppositely arranged indented sections **10B12** are arranged in an area of the middle rear end of the housing part **10B** and together

with indented section **10A12** form an area for the user to activate the thumbwheel **80**. Oppositely arranged support surfaces **10B13** are arranged on the body portion **10B5** and are configured to be slidably engaged by the surface **82** of the thumbwheel **80**. A half-slot or half-groove defined by surfaces **10B14** and **10B15** (together with half-groove formed by surfaces **10A14** and **10A15**) forms a guide groove which guides the sliding movement of the slide member **50** between an initial and final position (see Figs. 8 and 9). The slide member **50** contacts and/or substantially abuts stop surface **10B14** in the initial position shown in Fig. 8 (as a result of the biasing force of the spring **S3**) and contacts and/or substantially abuts stop surface **10B15** in the final position shown in Fig. 9 (as a result of the user causing compression of the spring **S3**). Oppositely arranged reinforcing ribs **10B16** are also utilized. A projection **10B17** is utilized to support and guide the movement of a middle rear portion of the holding member **70** (see Figs. 2 and 4). A rear portion of the housing part **10B** includes surface **10B19** which is configured to abut with surface **10A19** of the housing part **10A**, and a groove **10B22** which slidably receives therein projection **30B6**. Housing part **10B** also includes reinforcing projections **10B18**, **10B20** and **10B21**, and each of these projections utilize a semi-circular recess which slidably supports the lancet holding member **70**. The rear portion of the housing part **10B** also includes surface **10B23** which is configured to be slidably engaged by the inner surface of portion **30B1** as well as oppositely arranged guide surfaces **10B25** which are sized and configured to be slidably engaged by the inner surfaces of members **30B3**. The guide surfaces **10B25** extend into openings in the member **10B** so as to form slots **10B25a** (see Fig. 24). An elongated recess or groove **10B26** is formed in the member **10B5** and is sized to receive therein the spring **S3** and be slidably engaged by the projection **54** (see Fig. 12). A projection **10B27** is utilized to support and guide the movement of a front portion of the holding member **70**. As is apparent from Figs. 23-25, the housing part **10B** can preferably be a one-piece member and is most preferably a one-piece synthetic resin member. Of course, the member **10B** can also be an assembly of plural components provided it functions in a manner similar to that of the member shown in Figs. 23-25.

[0035] With reference to Figs. 26 and 27, it can be seen that the front cap **20** includes a skin contacting surface **25** which includes a lancet needle opening **24** sized and located to allow one of the lancet needles **LN** to pass or extend there through. The front cap **20** has an outer tapered generally circular surface **22**, a rear end **21**, and a generally planar front surface **23** The front cap **20** preferably include mechanisms, i.e., oppositely arranged projections **27**, arranged on inner generally cylindrical surface **26** to ensure that the front cap **20** is removably mounted to the grooves **G** of the front end of the housing **10**. A shoulder **28** is structured and arranged to be contacted by the end **53** of the slide member **50** (so as to allow the slide member **50** to pop-off the front cap **20**), and to abut

the ends **10A1** and **10B1** of the housing parts **10A** and **10B**. As is apparent from Figs. 26 and 27, the front cap **20** can preferably be a one-piece member and is most preferably a one-piece synthetic resin member. Of course, the front cap **20** can also be an assembly of plural components provided it functions in a manner similar to that of the member shown in Figs. 29 and 30.

[0036] With reference to Figs. 28-33, it can be seen that the back cap **30** includes two main parts, i.e., upper back cap portion **30A** and lower back cap portion **30B**. The upper portion **30A** includes a front end **30A1**, a gripping indentation **30A4**, a tapered and rounded portion **30A7**, a rear end **30A2**. The two projections **30A3** serve to guide the linear movement of the back cap **30** relative to the housing **10** by slidably engaging with the surfaces **10A25**. A centrally arranged projection **30A6** extends into the groove **10A22** and has an opening which receives therein the projection **30B8** of the back cap part **30B**. A bottom surface **30A5** is configured to abut the surface **30B5** of the part **30B** and has openings which receive therein the projection **30B9** of the back cap part **30B**. The lower portion **30B** includes a front end **30B1**, a gripping indentation **30B4**, a tapered and rounded portion **30B7**, a rear end **30B2**. The two projections **30B3** serve to guide the linear movement of the back cap **30** relative to the housing **10** by slidably engaging with the surfaces **10B25**. A centrally arranged projection **30B6** extends into the groove **10B22** and has a projection which extend into an opening in the projection **30A6** of the back cap part **30A**. A bottom surface **30B5** is configured to abut the surface **30A5** of the part **30A** and has projections which extend into the openings in surface **30A5**. The rear facing surface of the projection **30B6** is configured to be contacted by a front end of the spring **S2**. This allows the spring **S2** to bias the back cap **30** towards the position shown in Fig. 16 and automatically moves the back cap **30** back to the position shown in Fig. 16 when the user releases the back cap **30** from the position shown in Fig. 17. As is apparent from Figs. 28-33, the back cap **30** can preferably be a two-piece member and is most preferably a two-piece synthetic resin member. Of course, the back cap **30** can also be a one-piece member and/or an assembly of more than two components provided it functions in a manner similar to that of the member shown in Figs. 28-33.

[0037] With reference to Figs. 34-36, it can be seen that the depth adjustment member or thumb wheel **80** includes an upper bearing surface **81** which is configured to slidably engage with the projections **10A24**, a rear surface **82** which is configured to slidably engage with the surfaces **10B13**, and a rear surface **87** which is configured to slidably engage with the surface **10B24**. In this way, the thumb wheel **80** is axially retained within the housing **10**. A generally cylindrical projection **83** is sized to rotatably engaged with and mount to an opening formed in the projection **10A9**. The thumb wheel **80** also includes an outer surface **84** adapted to be frictionally engaged by a user's fingers

which allow a user to easily grip the thumb wheel **80** and rotate it relative to the housing **10** in each of a clockwise and counterclockwise directions. Any type of friction surface can also be utilized in the area **84**. The thumb wheel **80** also includes a main projection **85**. The main projection **85** includes a number or cam or stop surfaces **86a** – **86f** which function to control the depth of penetration of the lancet needle **LN** and/or which control the distance **PD** (see Fig. 4). The depth of penetration **PD** is adjusted or predetermined by the rotational position of the thumb wheel **80** relative to the housing **10** and more specifically by the rotational position of the surfaces **86a** – **86f** relative to the movably stop surface **74**. Maximum depth of penetration **PD** results when the projection **74** contacts stop surfaces **86a** whereas minimum depth of penetration **PD** results when the projection **74** contacts stop surface **86f**. The thumb wheel **80** also utilizes indicia **88** which functions to provide the lancet device **LD** with a system for indicating to the user the position of depth adjustment, i.e., the rotational position of the thumb wheel **80**, so that the user can determine whether to change the depth of penetration. An indicator, e.g., window **10A13**, is arranged on the housing **10** and allows the user to see the indicia **88**. By way of non-limiting example, the indicia value "1" (viewed in the window **10A13**) can correspond to the stop surface **86f** being located in a position allowing it to be contacted by the projection **74**; the indicia value "2" (viewed in the window **10A13**) can correspond to the stop surface **86e** being located in a position allowing it to be contacted by the projection **74**; the indicia value "3" (viewed in the window **10A13**) can correspond to the stop surface **86d** being located in a position allowing it to be contacted by the projection **74**; the indicia value "4" (viewed in the window **10A13**) can correspond to the stop surface **86c** being located in a position allowing it to be contacted by the projection **74**; the indicia value "5" (viewed in the window **10A13**) can correspond to the stop surface **86b** being located in a position allowing it to be contacted by the projection **74**; and the indicia value "6" (viewed in the window **10A13**) can correspond to the stop surface **86a** being located in a position allowing it to be contacted by the projection **74**. As is apparent from Figs. 34-36, the thumb wheel **80** can preferably be a one-piece member and is most preferably a one-piece synthetic resin member. Of course, the thumb wheel **80** can also be an assembly of plural components provided it functions in a manner similar to that of the member shown in Figs. 34-36.

[0038] With reference to Figs. 37-39, it can be seen that the trigger **40** includes a generally circular upper surface **41** which is configured to be contacted by a user finger. The trigger **40** also includes two oppositely arranged projections **43a** and **43b** which are configured to snap into the opening **10A10** and prevent removal of the trigger **40** once installed on the body portion **10A**. A generally circular projection **45** is configured to contact free end portion of the deflectable member

10A11. The projection **45** has a opening **47** which is aligned with a window **46** and together allows the user to view the red indicator **73** when the lancet device **LD** is in the trigger-set position. A generally rectangular projection **44** is configured to contact the deflectable member **72** and cause the shoulder of the deflectable member **72** (see Fig. 43) to disengage from the retaining shoulder **RS** after the lancet device **LD** is in a trigger-set position (see e.g., Fig. 3) and the trigger **40** is depressed. As is apparent from Figs. 37-39, the trigger **40** can preferably be a one-piece member and is most preferably a one-piece synthetic resin member. Of course, the trigger **40** can also be an assembly of plural components provided it functions in a manner similar to that of the member shown in Figs. 37-39.

[0039] With reference to Figs. 40 and 41, it can be seen that the slide or advance member **50** includes a generally circular button portion **51** which is configured to be contacted by a user finger. A front free end **52** is arranged on one end of a main portion **52** and is configured to contact the shoulder **28** of the front cap **20**. A rear projection **54** is arranged on another end of a main portion **52** and is configured to contact a rear end of the spring **S3** (see Fig. 12). A generally rectangular projection **55** is configured to extend into and slide within the slot **79** of member **70**. The member **55** has a front edge **58** that is configured to engage or contact a rear surface of the lancet **L** and has two oppositely arranged planar surfaces. A through slot **57** is formed on member **56** and is configured to slidably engage with cam projection **64** of locking member **60**. As is apparent from Figs. 40 and 41, the advance button **50** can preferably be a one-piece member and is most preferably a one-piece synthetic resin member. Of course, the member **50** can also be an assembly of plural components provided it functions in a manner similar to that of the member shown in Figs. 40 and 41.

[0040] With reference to Figs. 42-44, it can be seen that the lancet holding member **70** includes an annular front end **71a** having a generally cylindrical opening **LRO** sized to receive therein a lancet **L**, and a rear end **71b** which includes a shoulder **75** configured to retain therein a rear end of the spring **S2**. The member **70** has a generally cylindrical body portion **71c** sized to slidably engaged with support and guide surfaces of the housing parts **10A5** and **10B5**. The member **70** also includes a deflectable projection **72** which is configured to releasably lock to retaining shoulder **RS**. A color, e.g., red, indicator dot **73** is provided to indicate to the user when the holding member **70** is located in a trigger-set position. The member **70** also includes a stop projection **74** which is configured to contact one of the plurality of stop surfaces **86a – 86f**. A semi-cylindrical area **77a** is sized to receive therein the spring **S1** whereas semi-cylindrical area **76a** is sized to receive therein the spring **S2**. The elongated slot **77b** is sized to receive therein **10B9** and the elongated slot **76b** is

sized to receive therein **30B6**. The surface **77c** is configured to be contacted by a front end of the spring **S1**. An elongated slot **79** is sized to slidably receive therein the lancet ejecting portion **55** of the slide member **50**. The member **70** also includes a stop projection **78** which is configured to contact and slidably engage guide surface **10B28**, and can optionally engage with the stop projection **10B27**. As is apparent from Figs. 42-44, the member **70** can preferably be a one-piece member and is most preferably a one-piece synthetic resin member. Of course, the member **70** can also be an assembly of plural components provided it functions in a manner similar to that of the member shown in Figs. 42-44.

[0041] With reference to Figs. 45-47, it can be seen that the main spring **S1**, the return spring **S2** and the slide member return spring **S3** can have the form of helical wire compression springs. Each spring **S1-S3** is preferably be a one-piece member and is most preferably a one-piece spring metal member. Of course, the springs can also be made of any material provided they function in a manner similar to that of the members shown in Figs. 45-47.

[0042] With reference to Figs. 48 and 49, it can be seen that the locking member **60** includes a rear end **61** having an opening **62** which receives therein projection **10B10** and a forward end **63**. An upstanding elongated projection **64** is configured to slidably engage with recess **57** of the slide **50**. Such engagement causes pivoting movement of the end **63** about opening **62** between a position wherein the projection **65** locks with projection **78** (see Fig. 10) and an initial position wherein the projection **65** does not contact projection **78**. An opposite facing surface to surface **63** is configured to slidably engage with a generally planar surface **10B11** (see Fig. 11). As is apparent from Figs. 48 and 49, the locking member **60** can preferably be a one-piece member and is most preferably a one-piece synthetic resin member. Of course, the member **60** can also be an assembly of plural components provided it functions in a manner similar to that of the member shown in Figs. 48 and 49.

[0043] One or more of the parts of the lancet device **LD** such as, e.g., the housing **10** and front cap **20** can preferably made transparent and/or translucent so that a user will clearly be able to see internal components. The device can also utilize one or more features or modifications disclosed in US 2006/0173478 to SCHRAGA, the disclosure of which is hereby expressly incorporated by reference in its entirety.

[0044] All the parts of the lancet device **LD**, with the exception of the springs and needles (which can respectively be made of spring steel and stainless steel), may be made from plastic materials and can be formed using conventional injection molding techniques or other known manufacturing methods. Bay way of non-limiting example, all or most of the parts such as the housing, trigger, front and back caps, thumb wheel, advance button, slide plate, lancet engaging

member, locking member can be made of ABS plastic with the exception of the springs (which can be stainless steel) and the lancet holding member which can be made of polyoxymethylene (Delrin plastic). However, when practical, other materials and manufacturing processes may also be utilized.

[0045] It is noted that the foregoing examples have been provided merely for the purpose of explanation and are in no way to be construed as limiting of the present invention. While the present invention has been described with reference to an exemplary embodiment, it is understood that the words which have been used herein are words of description and illustration, rather than words of limitation. Changes may be made, within the purview of the appended claims, as presently stated and as amended, without departing from the scope and spirit of the present invention in its aspects. Although the present invention has been described herein with reference to particular means, materials and embodiments, the present invention is not intended to be limited to the particulars disclosed herein; rather, the present invention extends to all functionally equivalent structures, methods and uses, such as are within the scope of the appended claims.

WHAT IS CLAIMED IS:

1. A lancet device comprising:

a housing;

a removable front cap mounted to the housing;

a lancet holding member;

a trigger;

a system for placing the lancet device in a trigger-set or armed position;

a depth adjustment system comprising a member that is at least partially rotatably mounted and that has an axis of rotation arranged substantially perpendicular to a center axis of the lancet holding member; and

an ejection system for at least one of:

preventing axial movement of the lancet holding member; and

removing or ejecting a lancet from the lancet holding member.

2. The lancet device of claim 1, wherein the ejection system comprises a manually activated slide button.

3. The lancet device of claim 1, wherein the ejection system each of prevents axial movement of the lancet holding member and removes or ejects the lancet from the lancet holding member.

4. The lancet device of claim 1, wherein the member that is at least partially rotatably mounted comprises a thumbwheel having plural cam or stop surfaces.

5. The lancet device of claim 1, wherein the member that is at least partially rotatably mounted comprises a thumbwheel having indicia.

6. The lancet device of claim 1, wherein the member that is at least partially rotatably mounted comprises a thumbwheel having indicia which is visible through an opening located in the housing.

7. The lancet device of claim 1, wherein the member that is at least partially rotatably mounted comprises a thumbwheel having portions which can be gripped by a user from outside of the housing.

8. The lancet device of claim 1, wherein the member that is at least partially rotatably mounted comprises a thumbwheel having oppositely arranged portions which project outside of the housing.

9. The lancet device of claim 1, further comprising a first spring for causing movement of the lancet holding member towards a puncturing position and a second for causing a back cap to move towards an initial position from a retracted position.

10. The lancet device of claim 1, further comprising a first spring for causing movement of the lancet holding member towards a puncturing position, a second for causing a back cap to move towards an initial position from a retracted position, and a third spring for causing a slide member of the ejection system to move towards an initial position from an extended position.

11. A method of puncturing a surface of skin using the lancet device of claim 1, the method comprising:

arranging the lancet device adjacent against a user's skin; and

triggering the lancet device so that a lancet is caused to penetrate the user's skin.

12. A lancet device comprising:

a housing;

a removable front cap mounted to the housing;

a lancet holding member having a front end adapted to receive therein a removable lancet;

a trigger;

a system for placing the lancet device in a trigger-set or armed position;

a depth adjustment system comprising a member having plural cam surfaces; and

an ejection system for at least one of:

preventing axial movement of the lancet holding member;

removing or ejecting a lancet from the lancet holding member; and

removing or ejecting the front cap.

13. The lancet device of claim 12, wherein the ejection system comprises a manually activated slide button.

14. The lancet device of claim 12, wherein the ejection system each of prevents axial movement of the lancet holding member, removes or ejects the lancet from the lancet holding member, and removes or ejects the front cap.

15. The lancet device of claim 12, wherein the member is at least partially rotatably mounted and comprises a thumbwheel.

16. The lancet device of claim 15, wherein the thumbwheel comprises indicia.

17. The lancet device of claim 16, wherein the indicia is visible through an opening located in the housing.

18. The lancet device of claim 15, wherein the thumbwheel one of has portions which can be gripped by a user from outside of the housing, and oppositely arranged portions which project outside of the housing.

19. The lancet device of claim 12, further comprising a first spring for causing movement of the lancet holding member towards a puncturing position and a second for causing a back cap to move towards an initial position from a retracted position.

20. The lancet device of claim 12, further comprising a first spring for causing movement of the lancet holding member towards a puncturing position, a second for causing a back cap to move towards an initial position from a retracted position, and a third spring for causing a slide member of the ejection system to move towards an initial position from an extended position.

21. A method of puncturing a surface of skin using the lancet device of claim 12, the method comprising:

arranging the lancet device adjacent against a user's skin; and

triggering the lancet device so that a lancet is caused to penetrate the user's skin.

22. A lancet device comprising:

a housing having an ergonomic shape;

a removable front cap mounted to the housing;

a movably mounted lancet holding member having a front end adapted to receive therein a removable lancet;

a trigger arranged on a side wall of the hosing;

a system for placing the lancet device in a trigger-set or armed position;

a depth adjustment system comprising a member having plural cam surfaces;

a locking member configured to prevent axial movement of the lancet holding member; and

an ejection system configured to remove or eject a lancet from the lancet holding member.

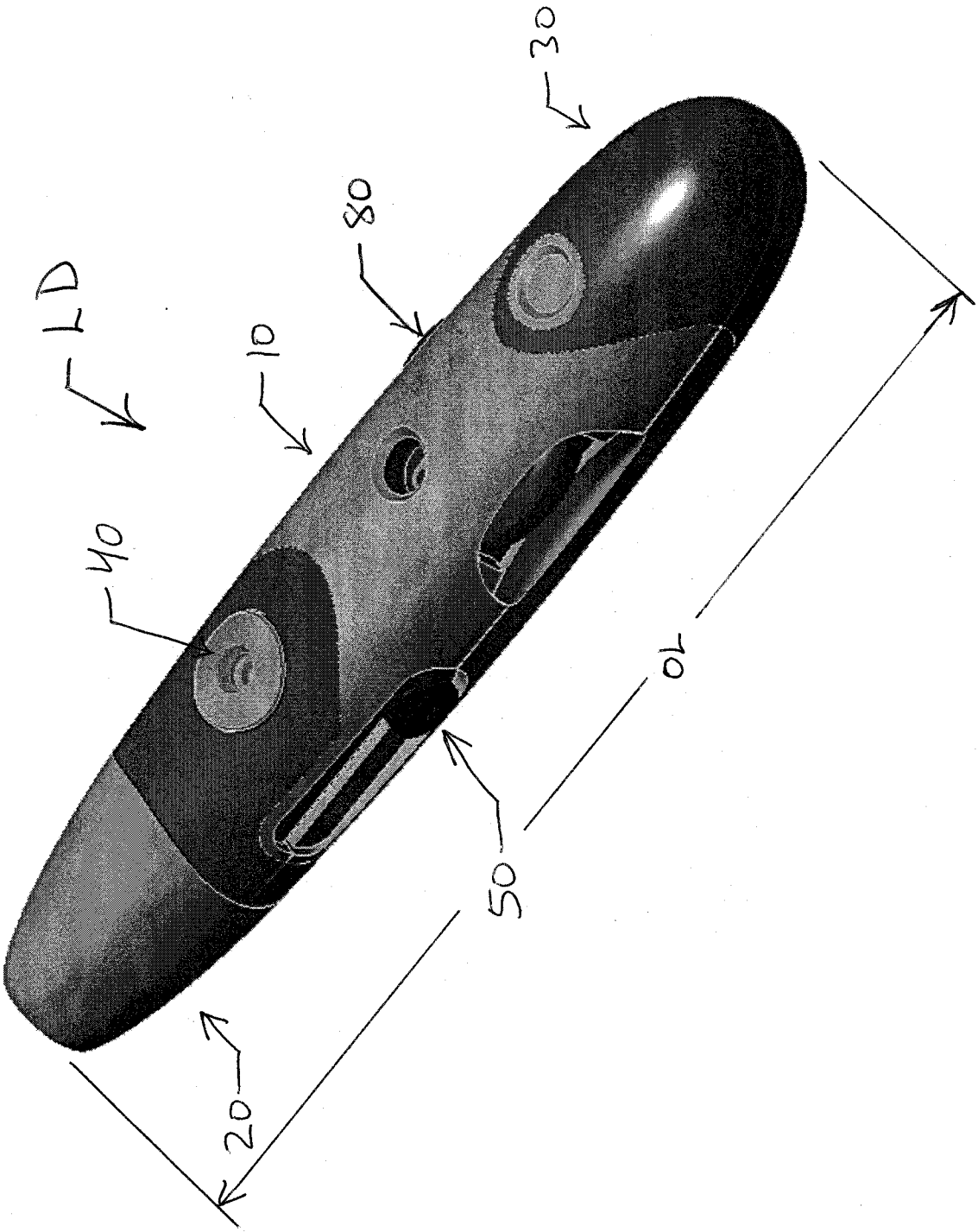


Fig. 1

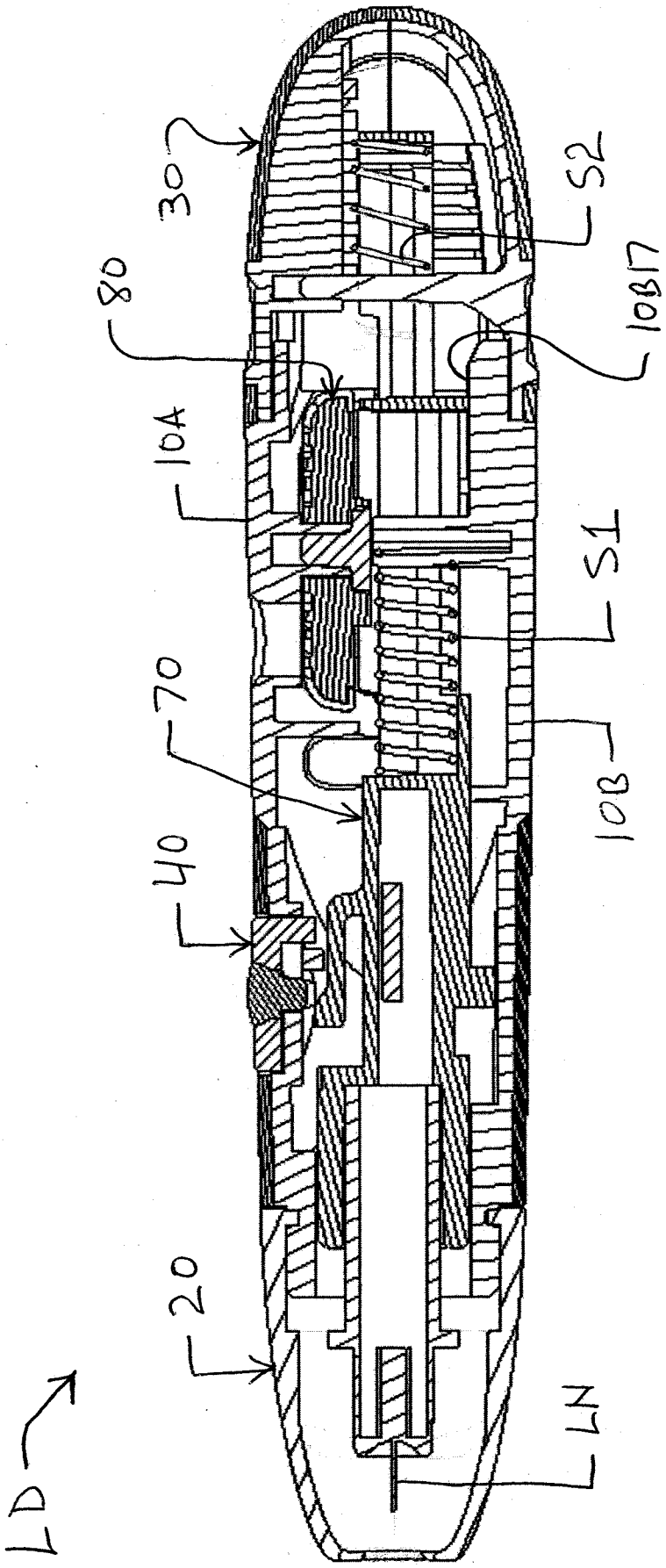
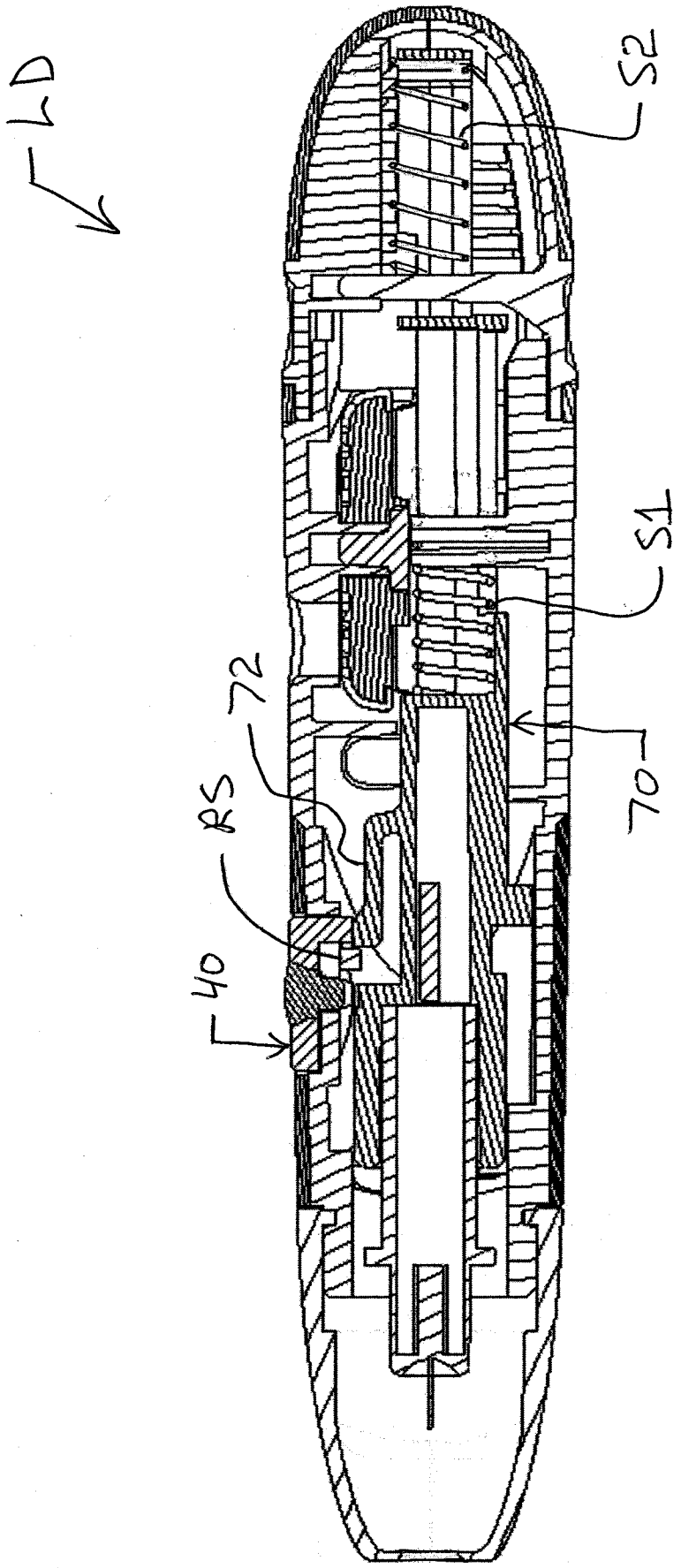


Fig. 2



Armed state

Fig. 3

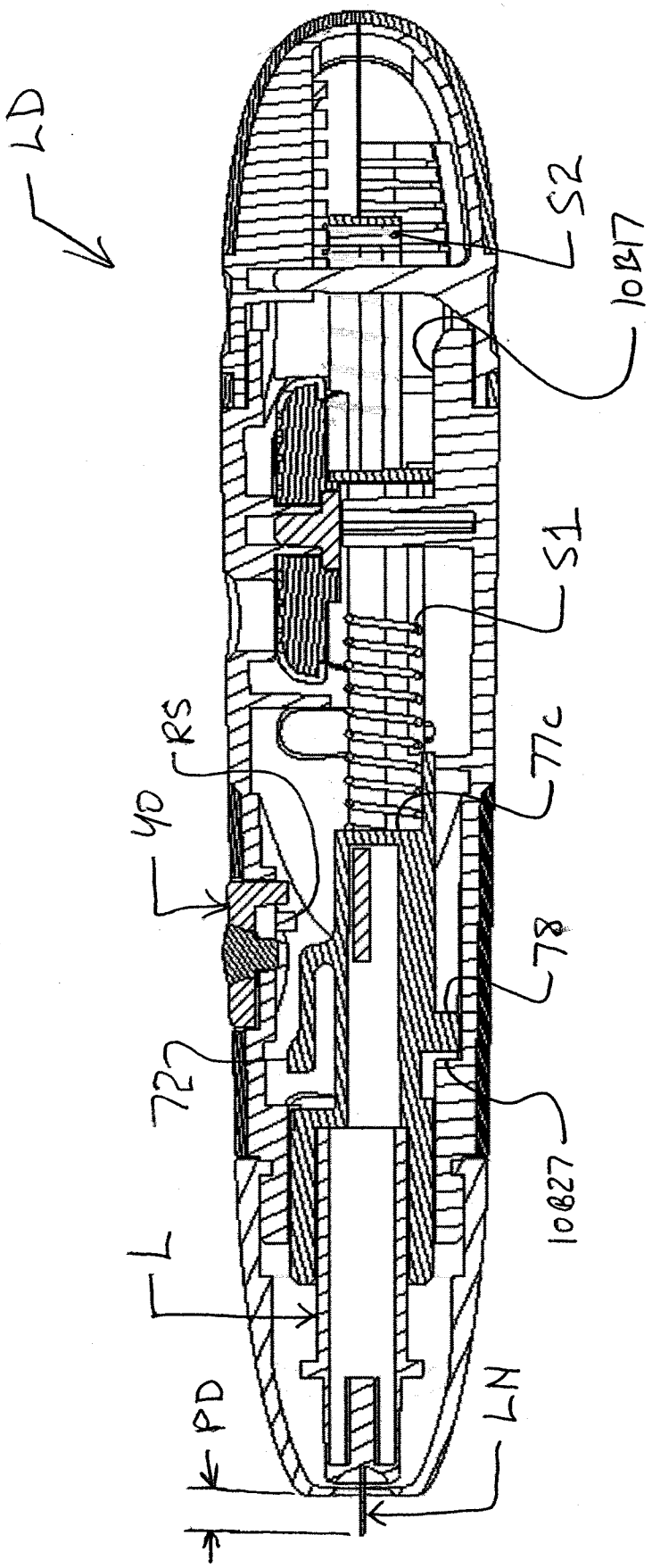


Fig. 4

Fired state

Fig. 6

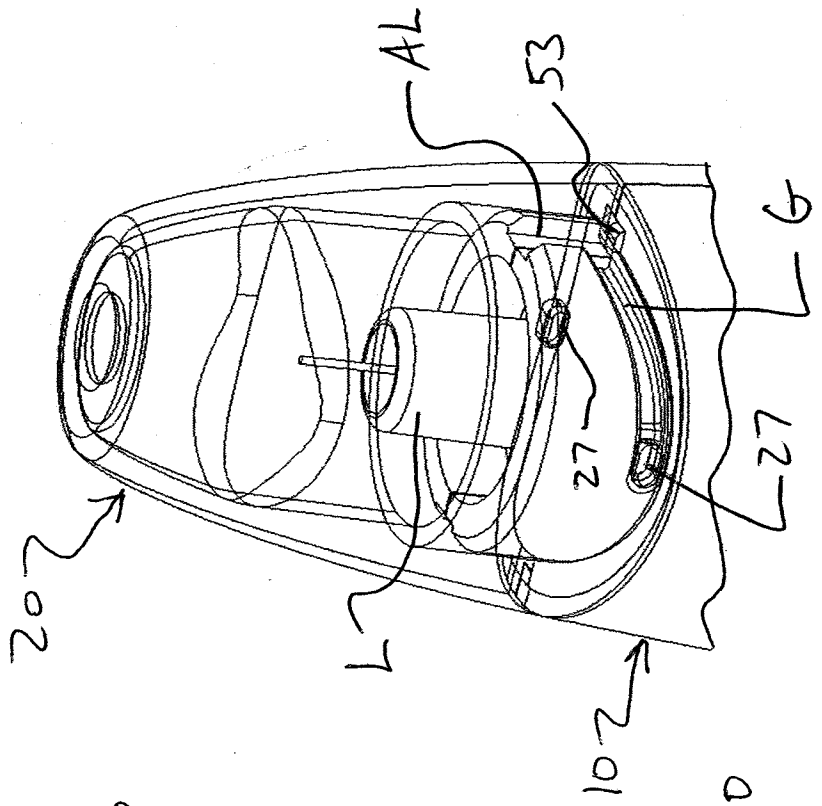


Fig. 5

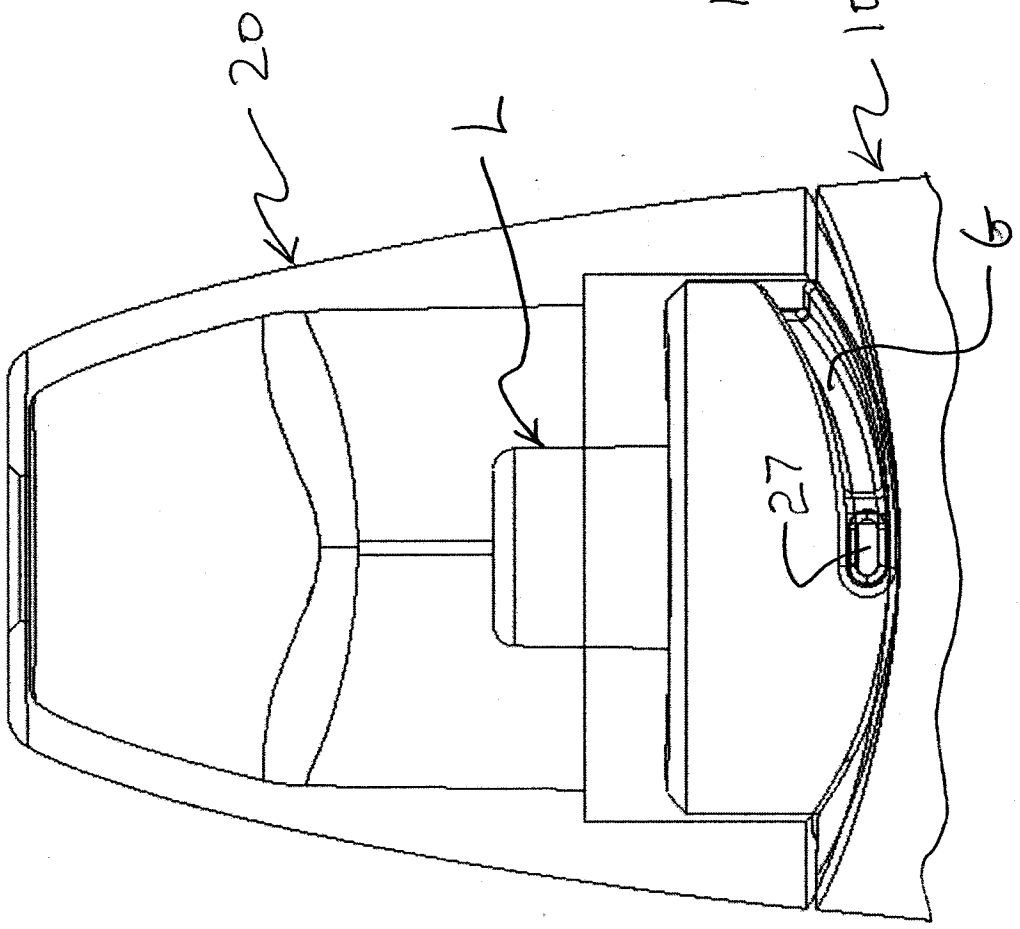
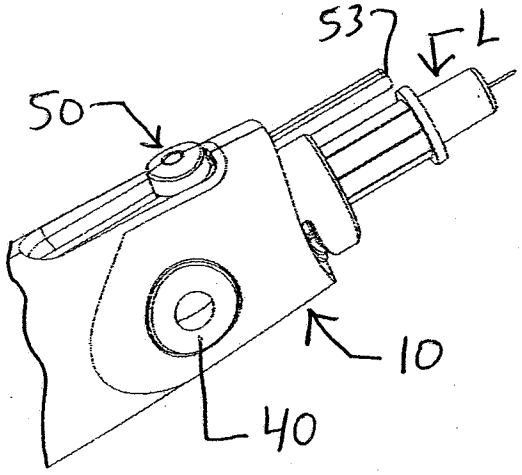


Fig. 7



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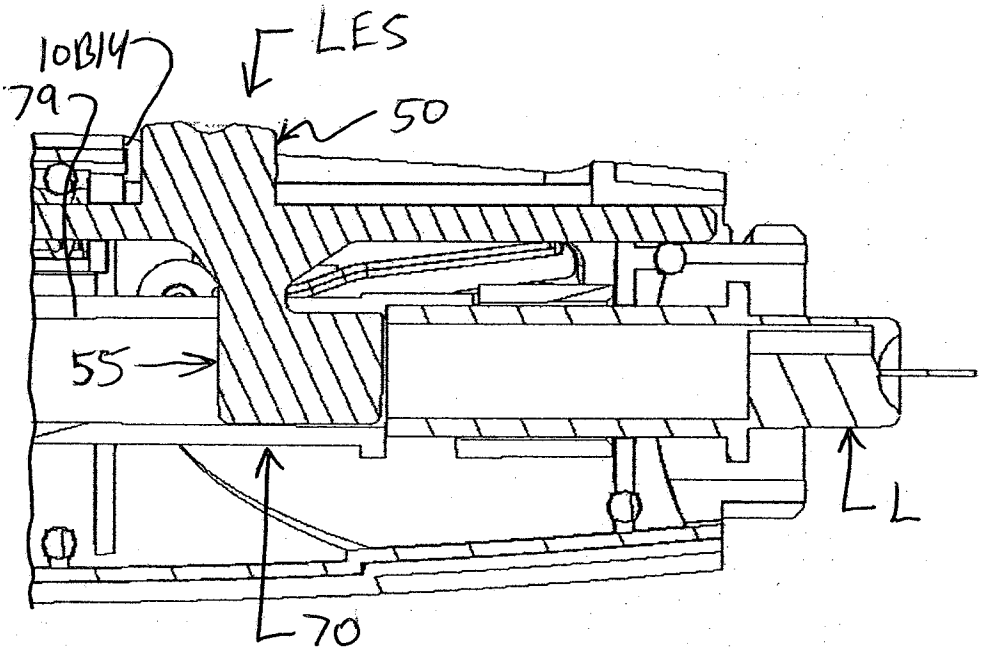

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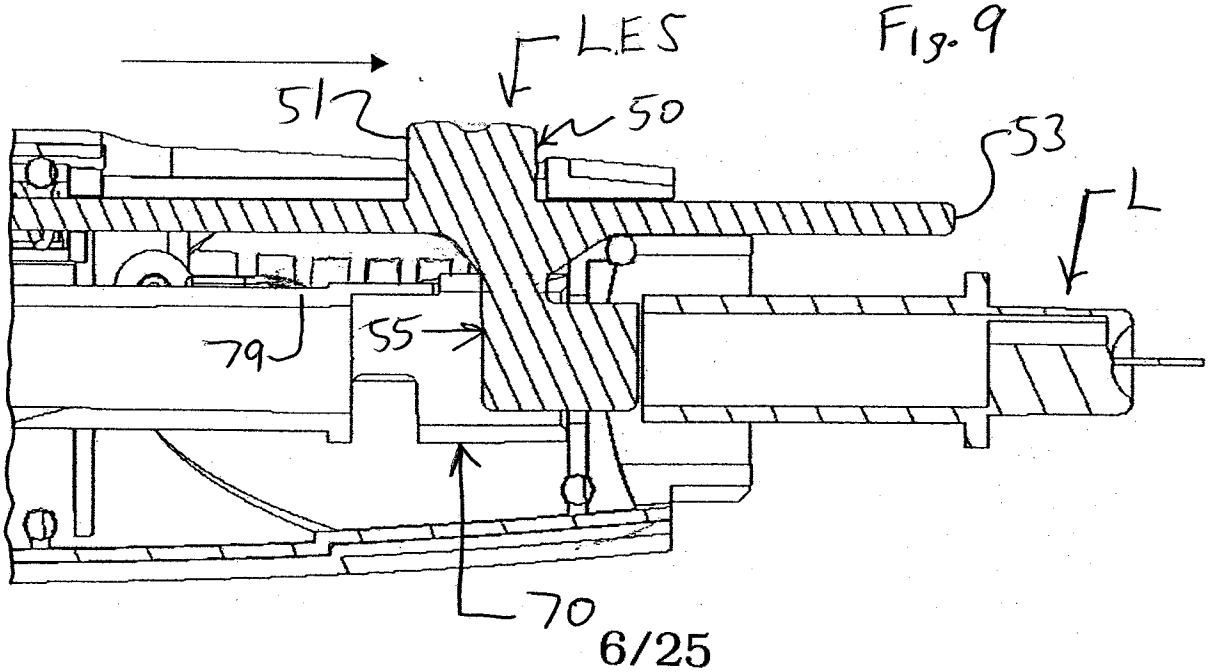


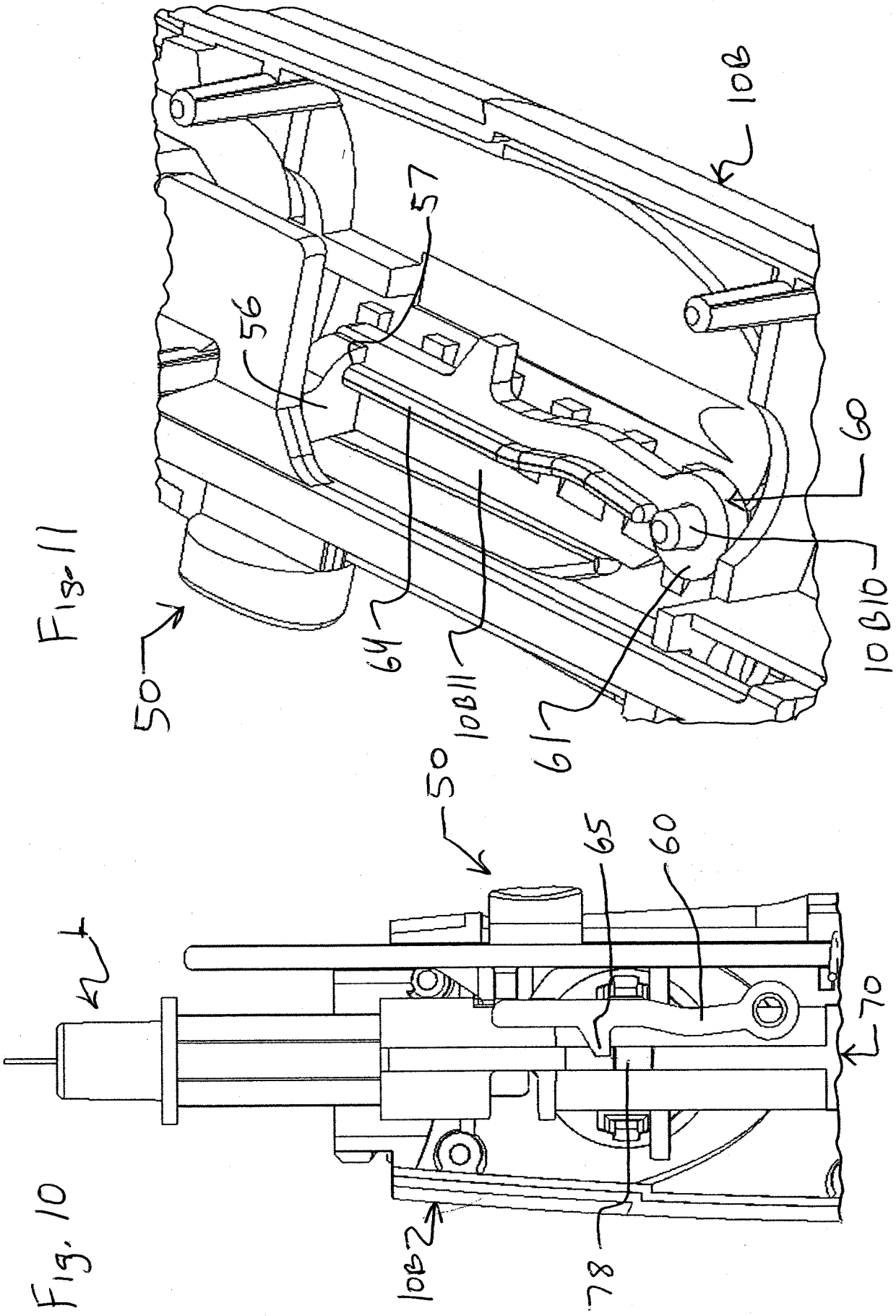
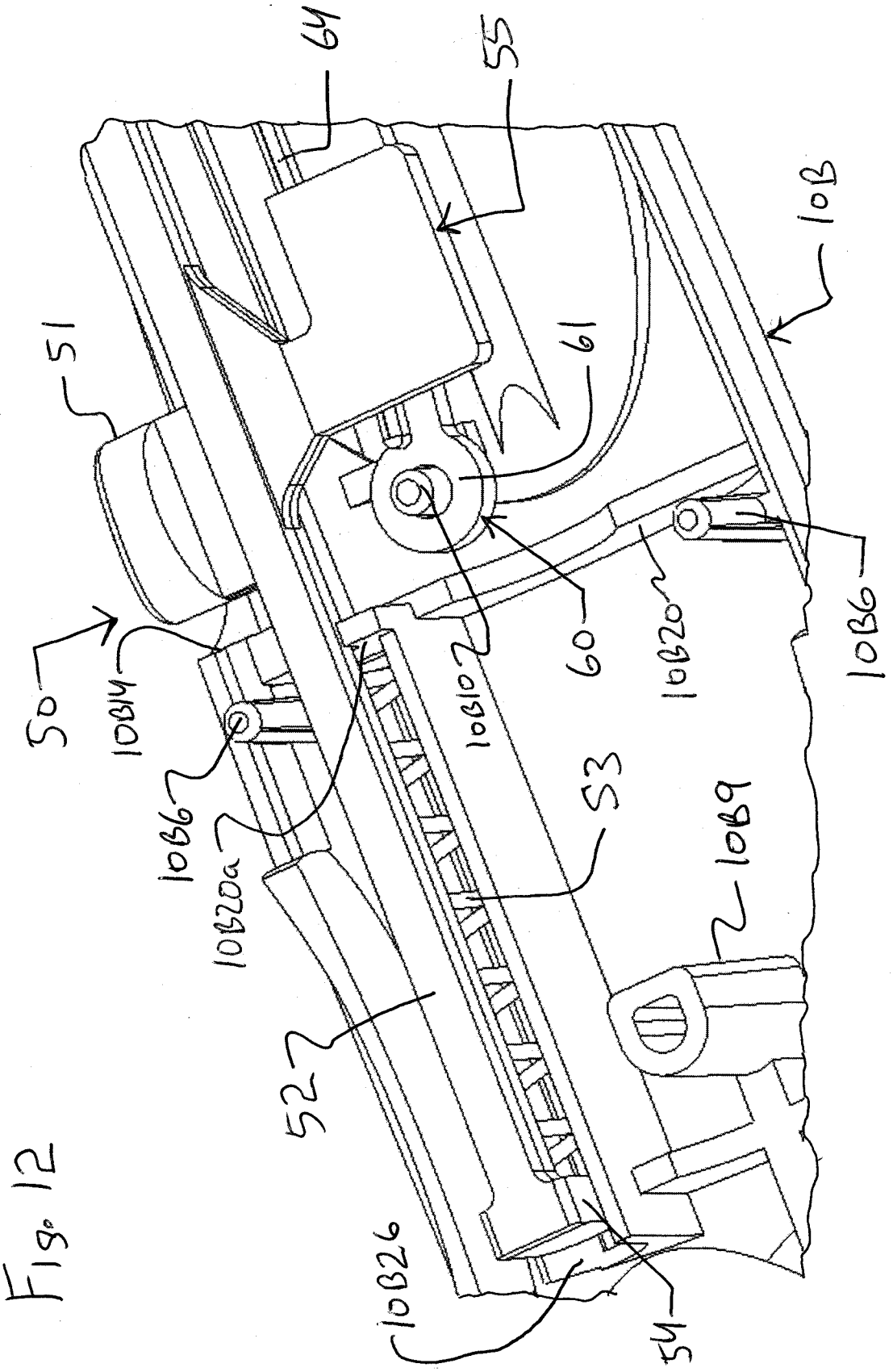


Fig. 11

Fig. 10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54

Fig. 12

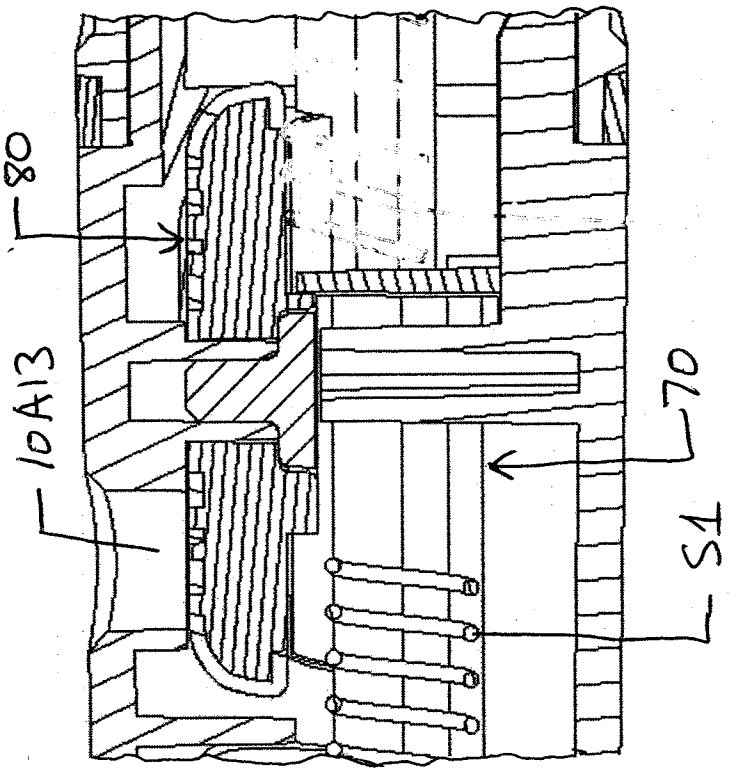


Fig. 14

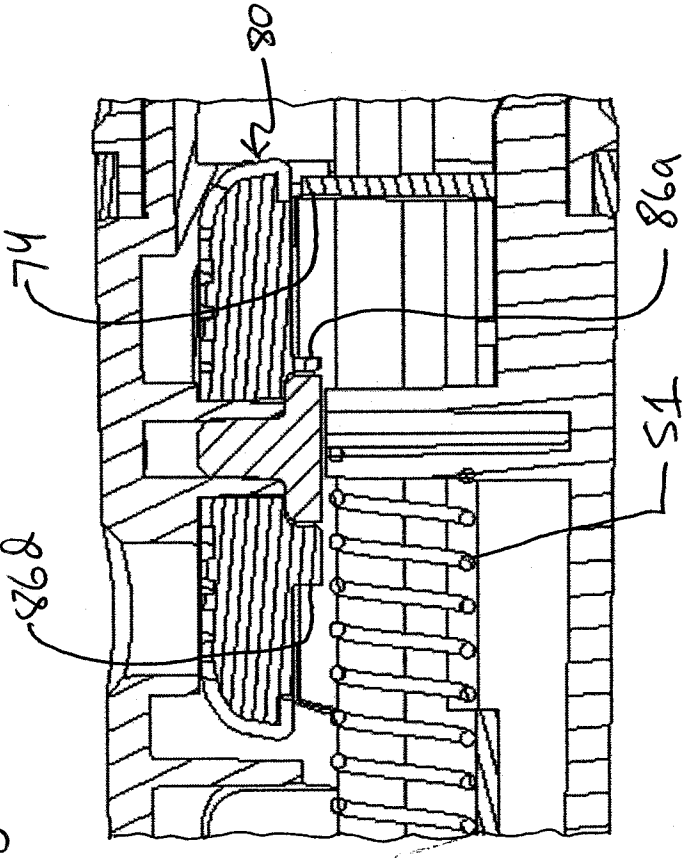


Fig. 13

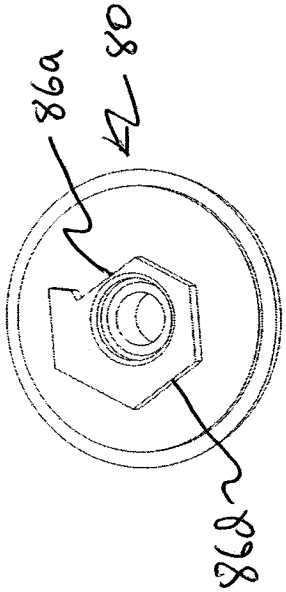


Fig. 15

Arming

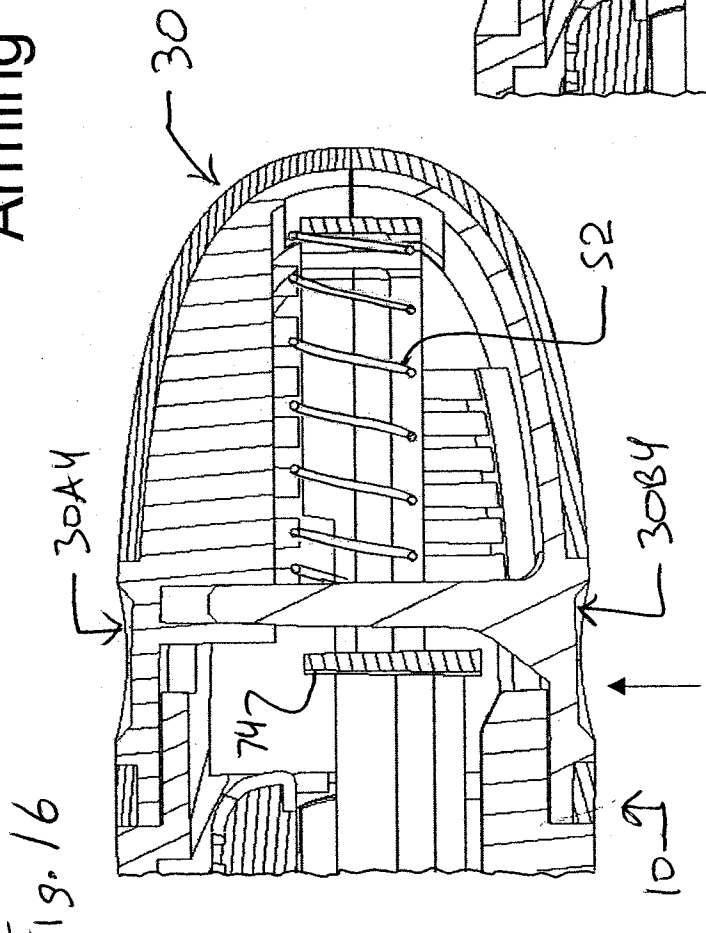


Fig. 16

Grabbing location (both sides).

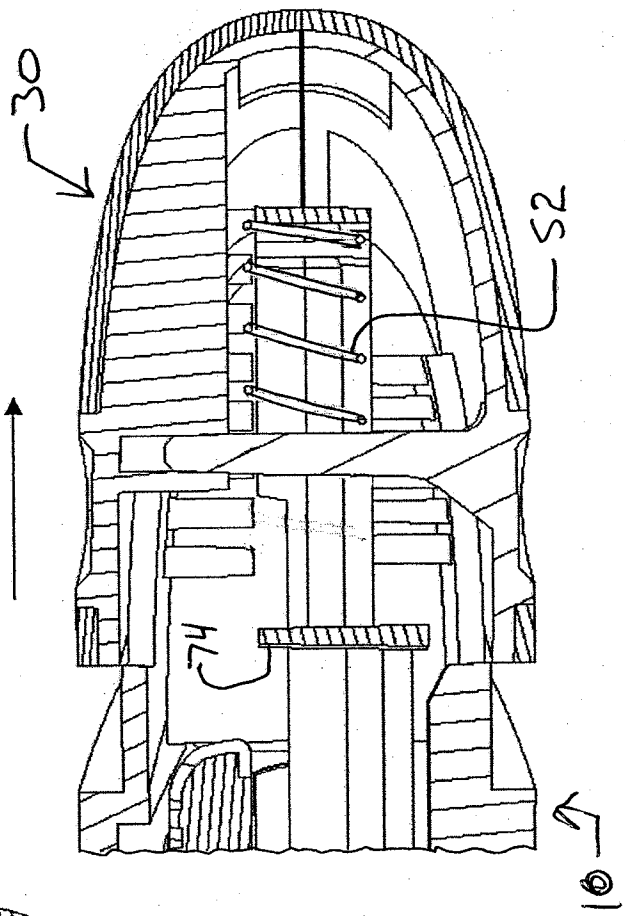


Fig. 17

Actuator is pulled back to arm.
Assume return spring is compressed.

Fig. 19

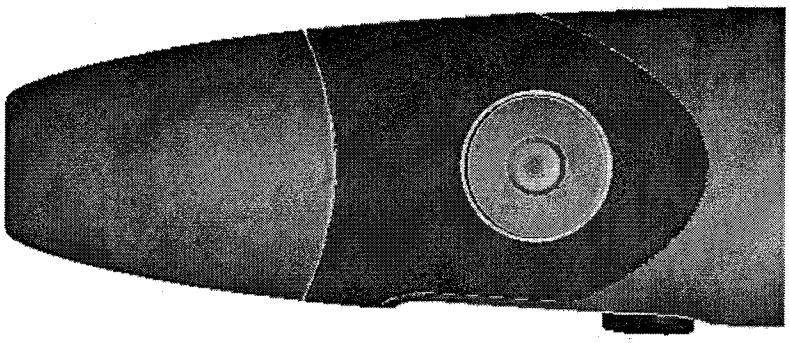
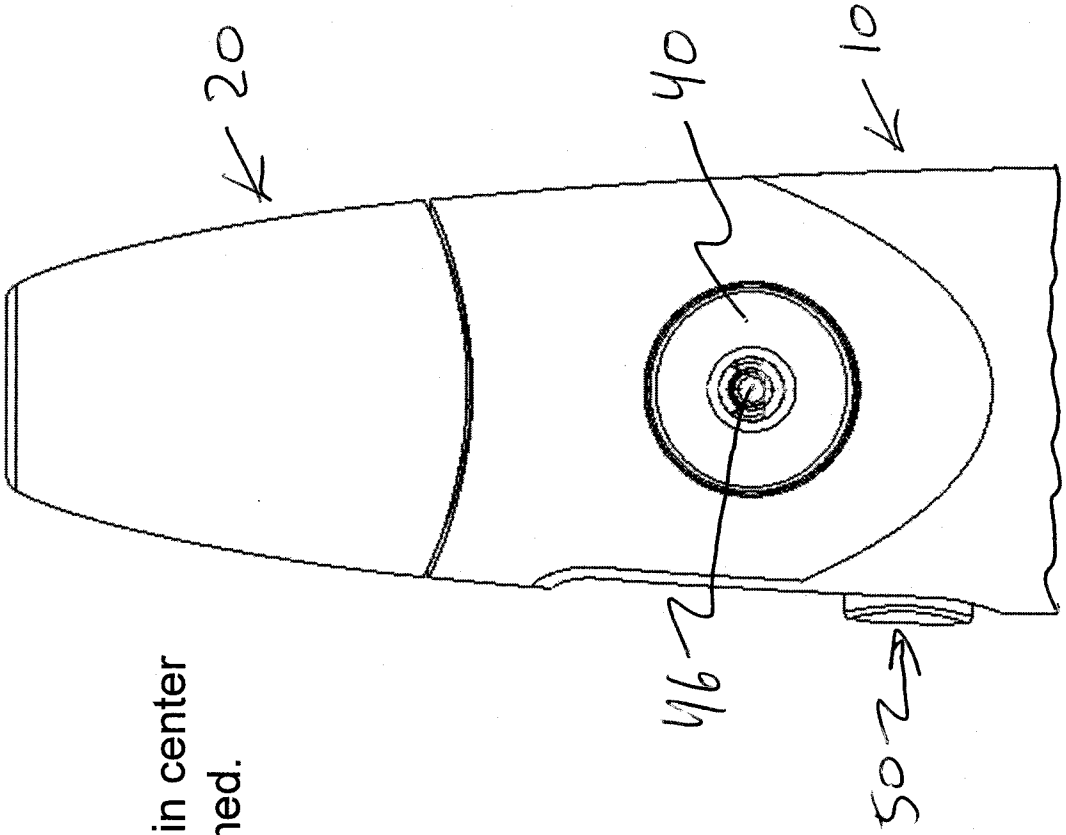
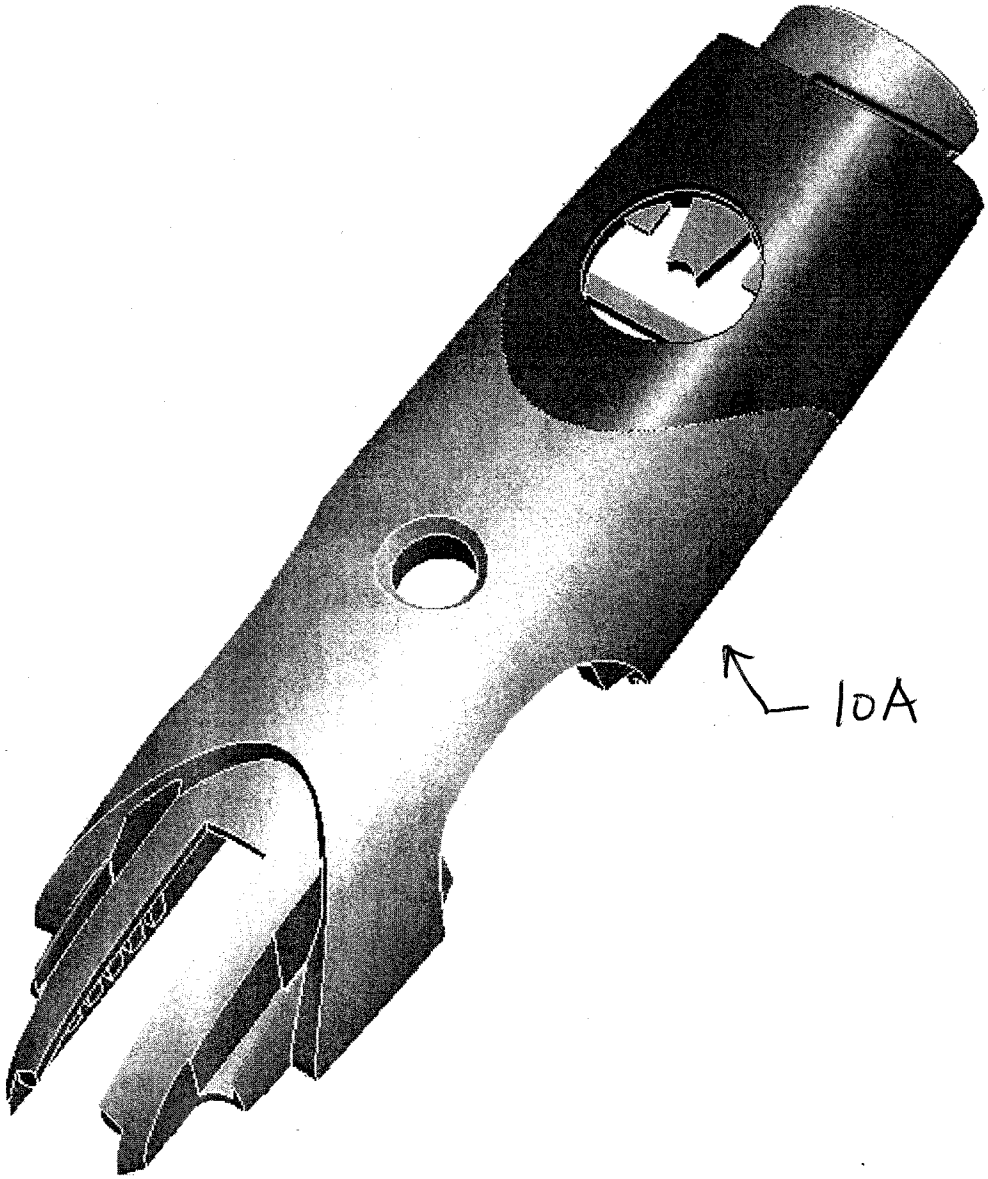


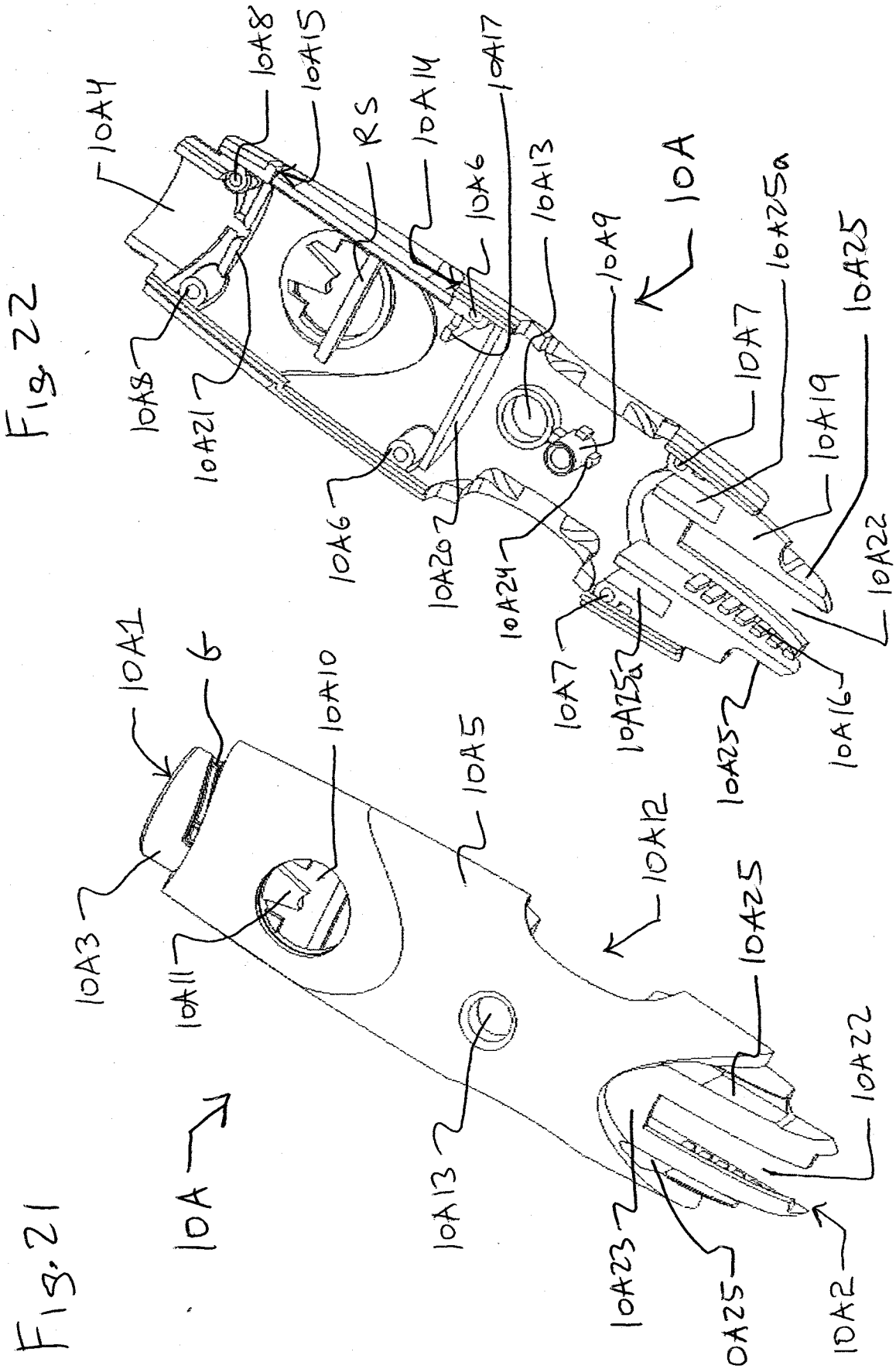
Fig. 18



Red dot to appear in center of button when armed.

Fig. 20

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10A16
10A25
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10A1
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10A10
10A5
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10A11
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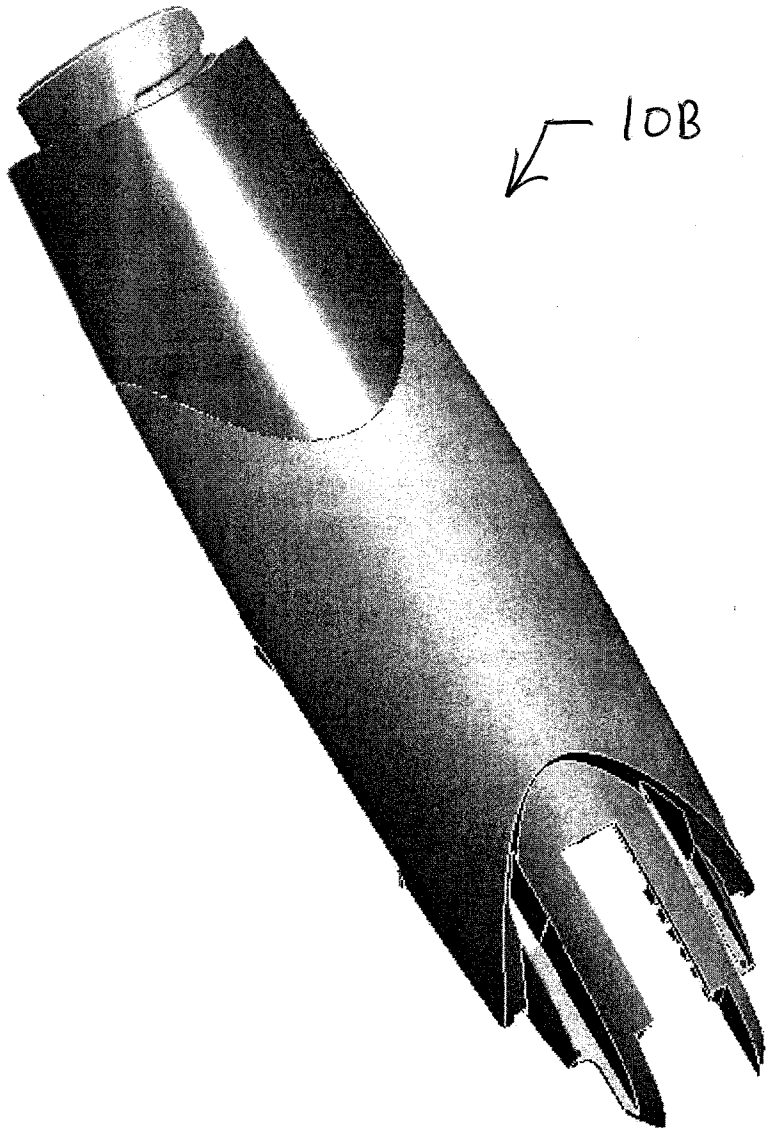
10A22
10A23
10A25
10A2

Fig. 22

Fig. 21

Fig. 23



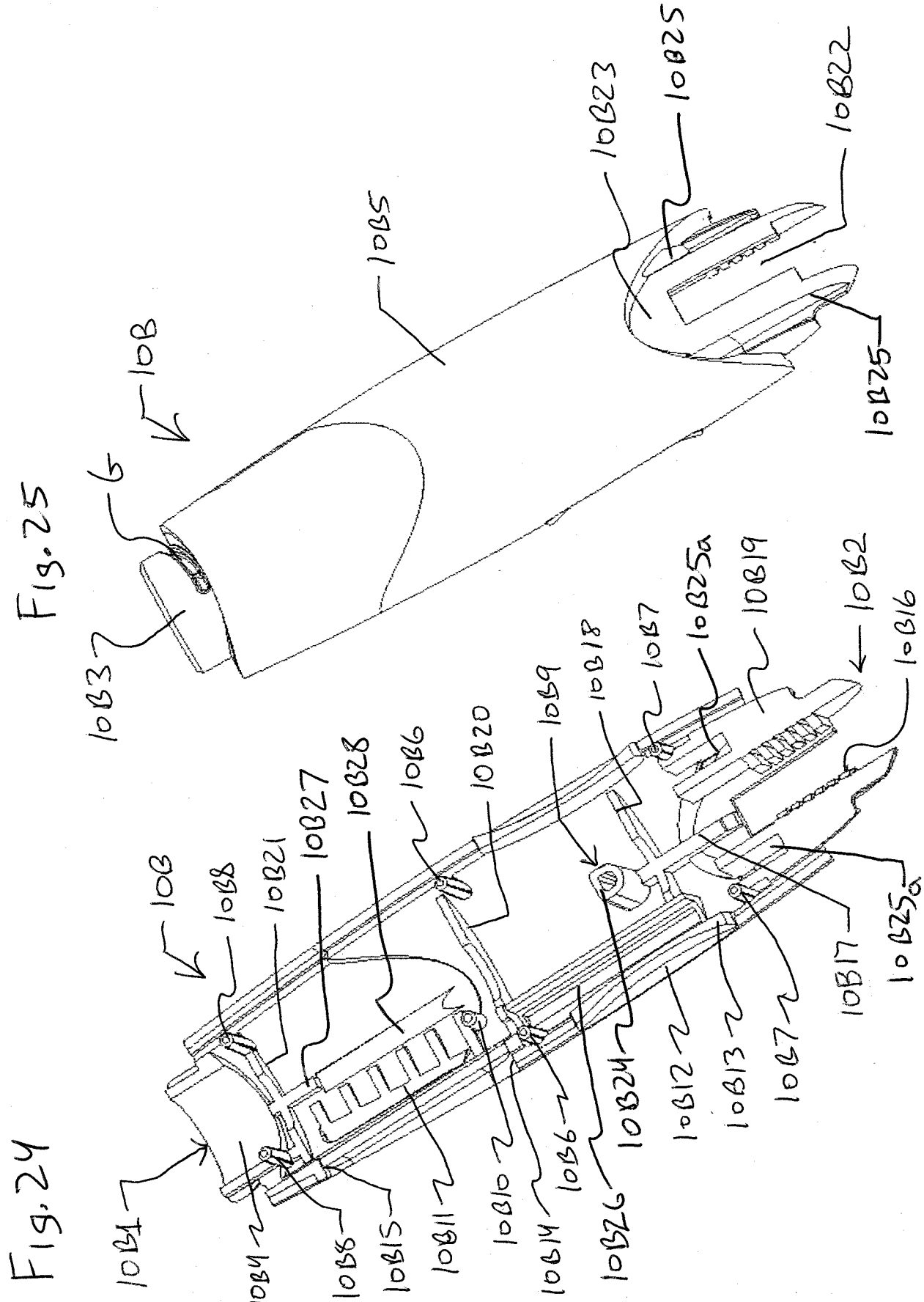

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Fig. 24

Fig. 25

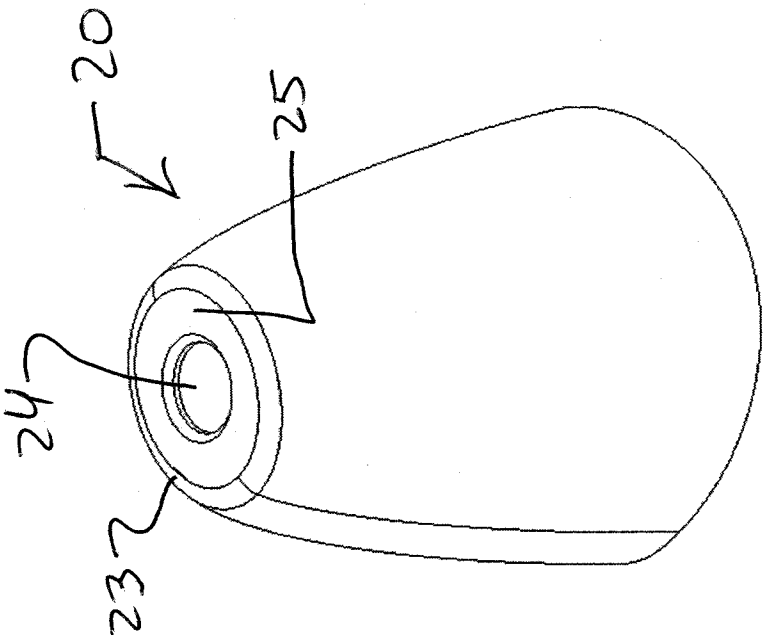


Fig. 27

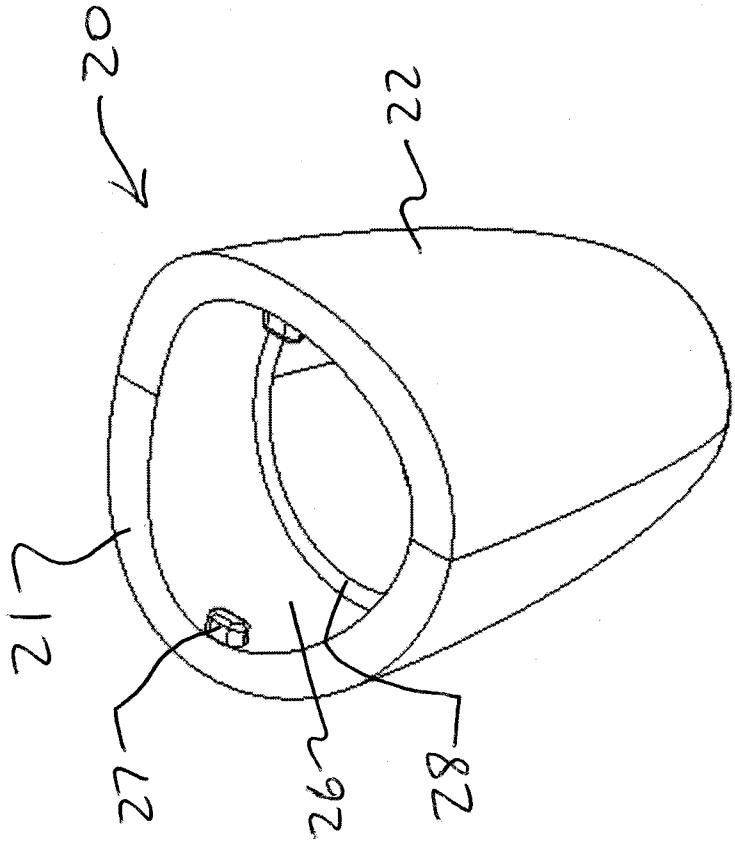


Fig. 26

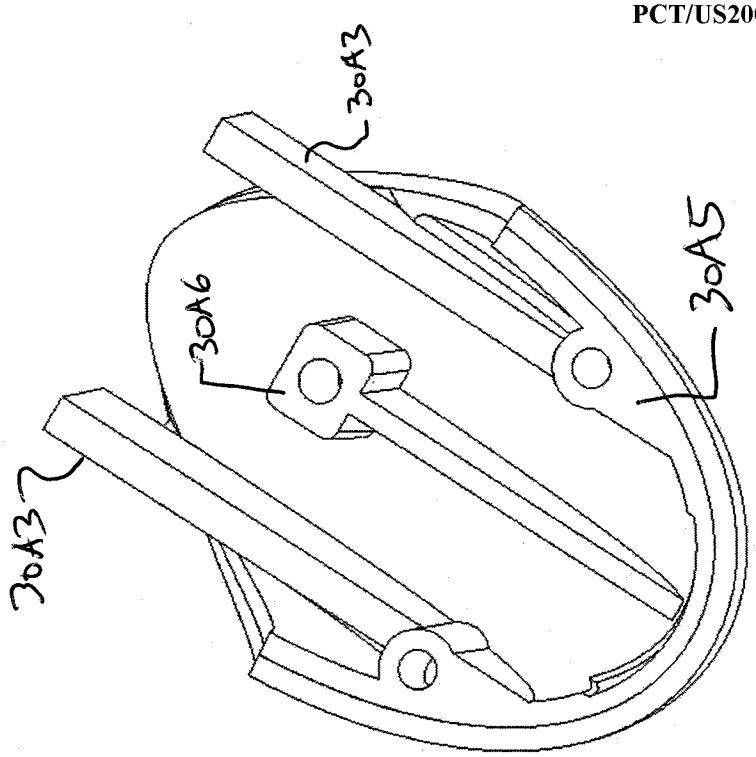


Fig. 30

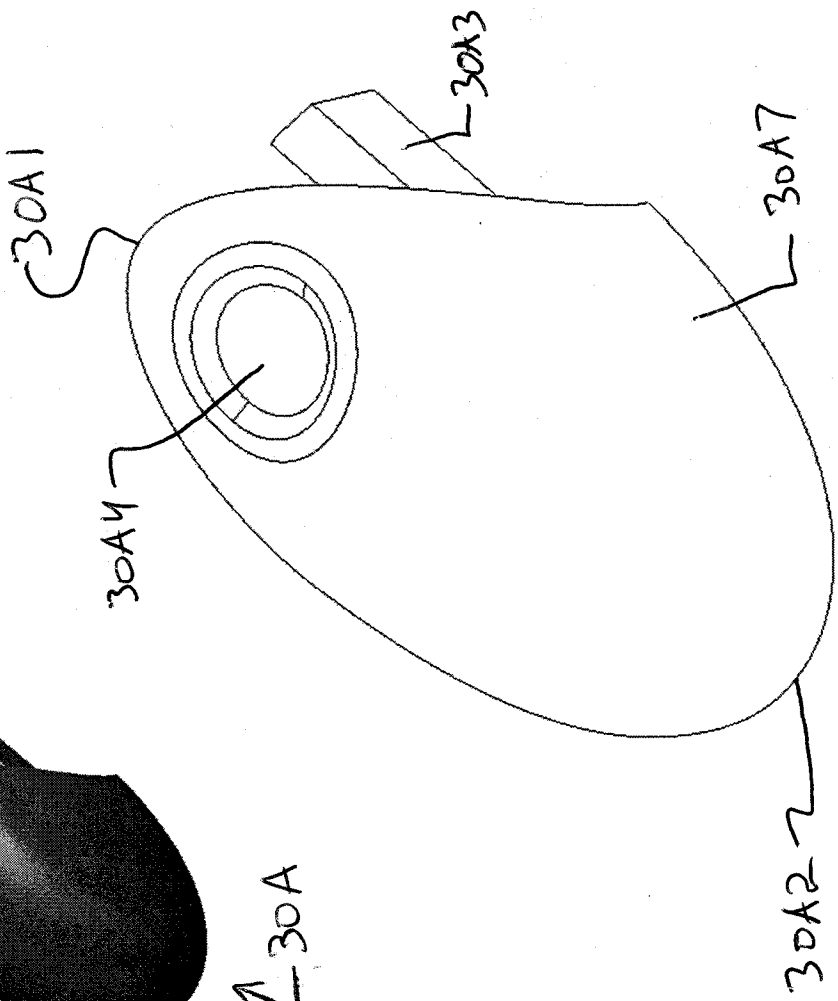


Fig. 29

Fig. 28

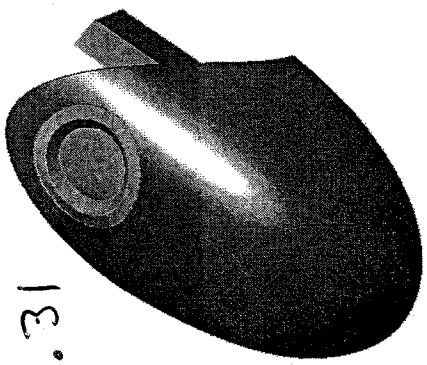


Fig. 31

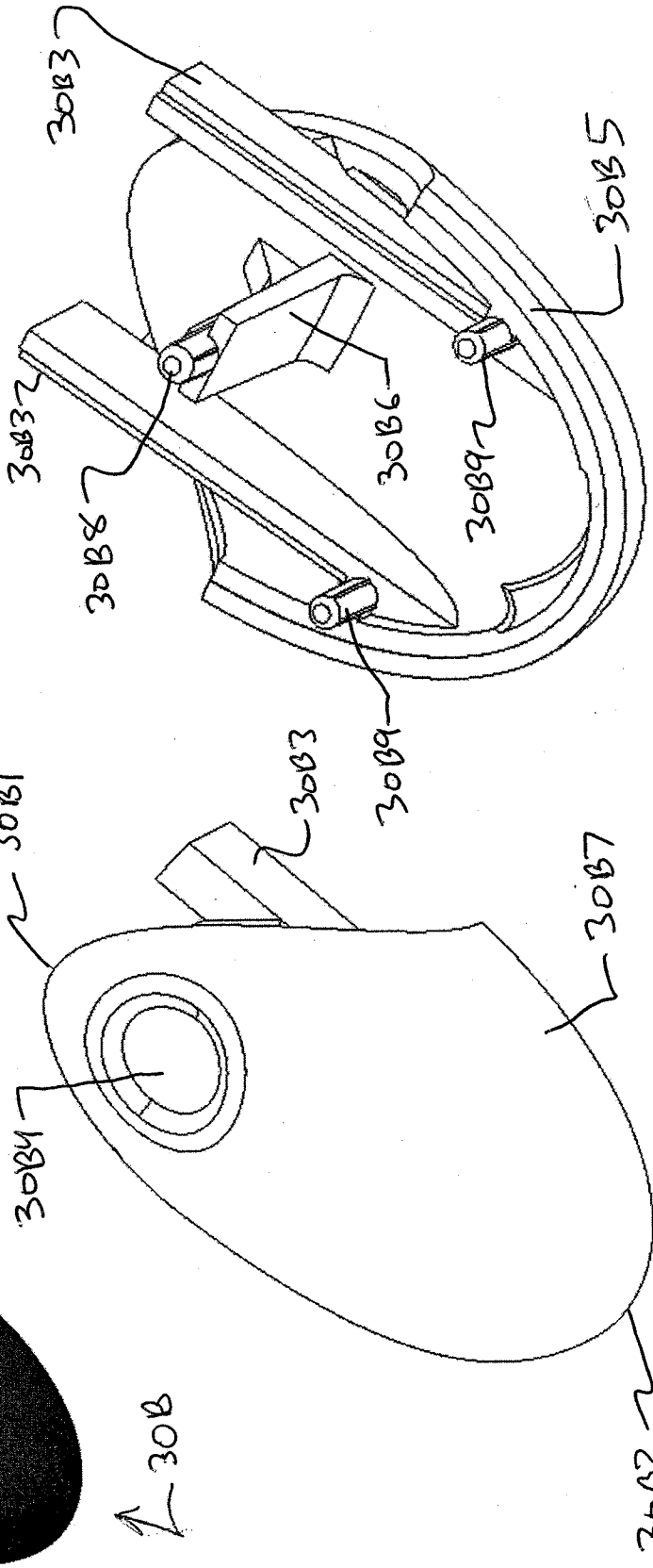


Fig. 32

Fig. 33

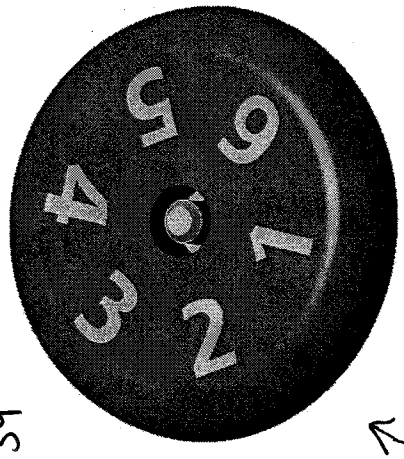


Fig. 34

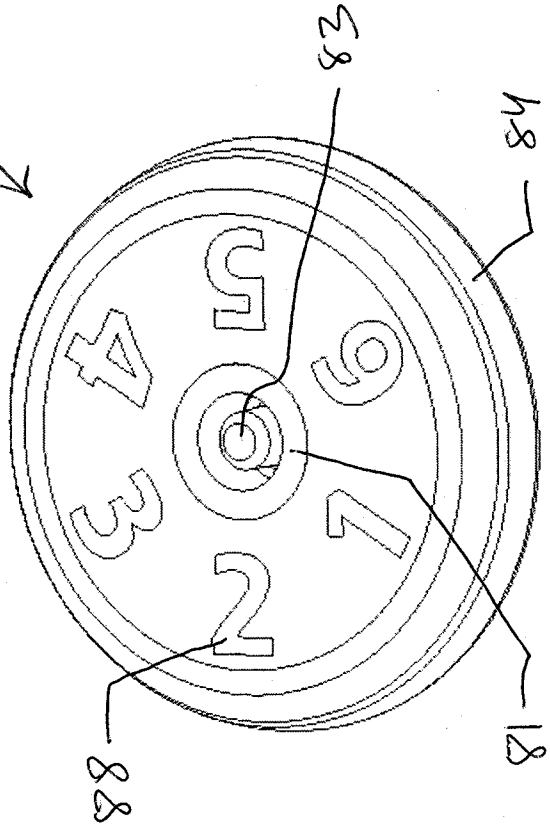


Fig. 35

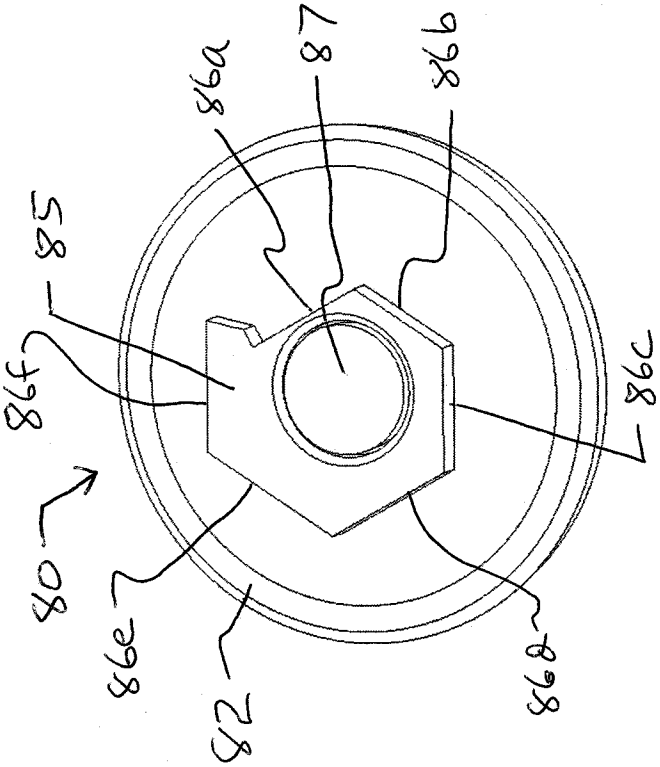


Fig. 36

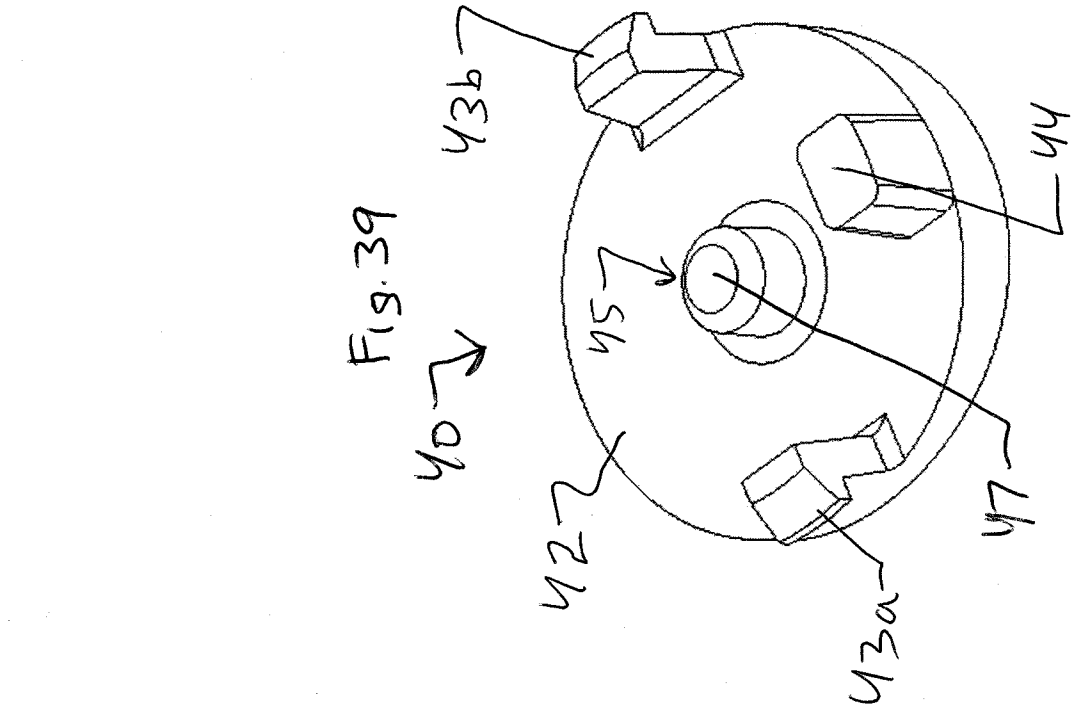


Fig. 39

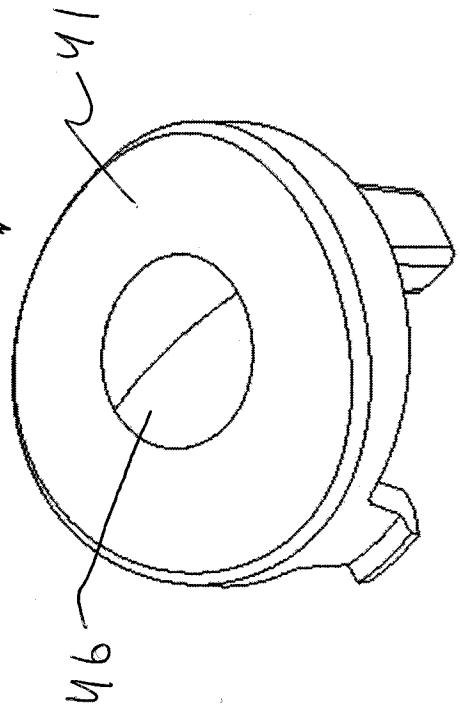


Fig. 38

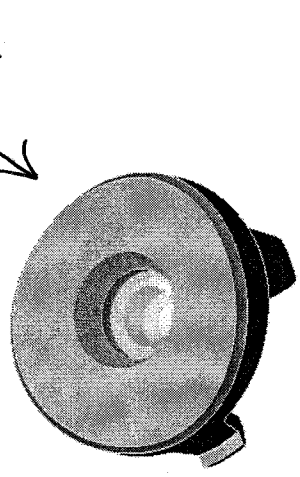


Fig. 37

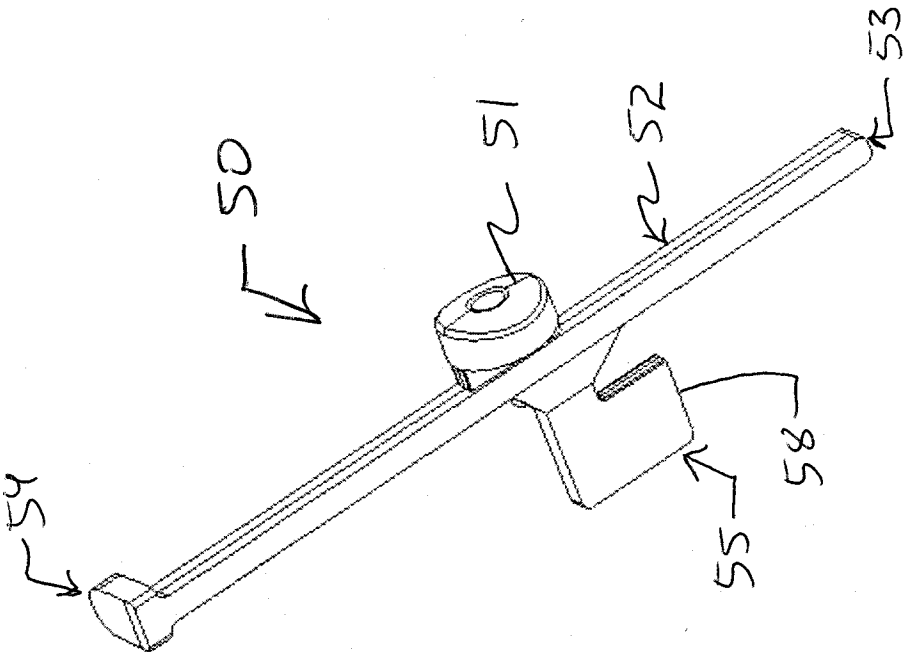


Fig. 41

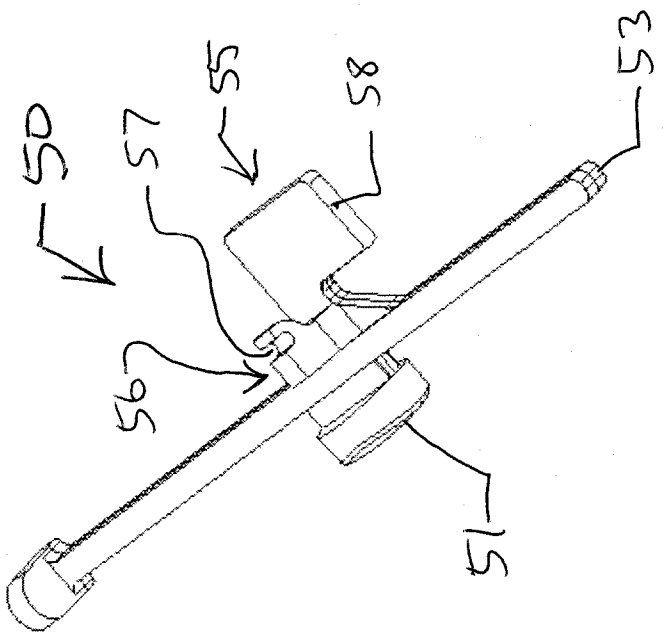
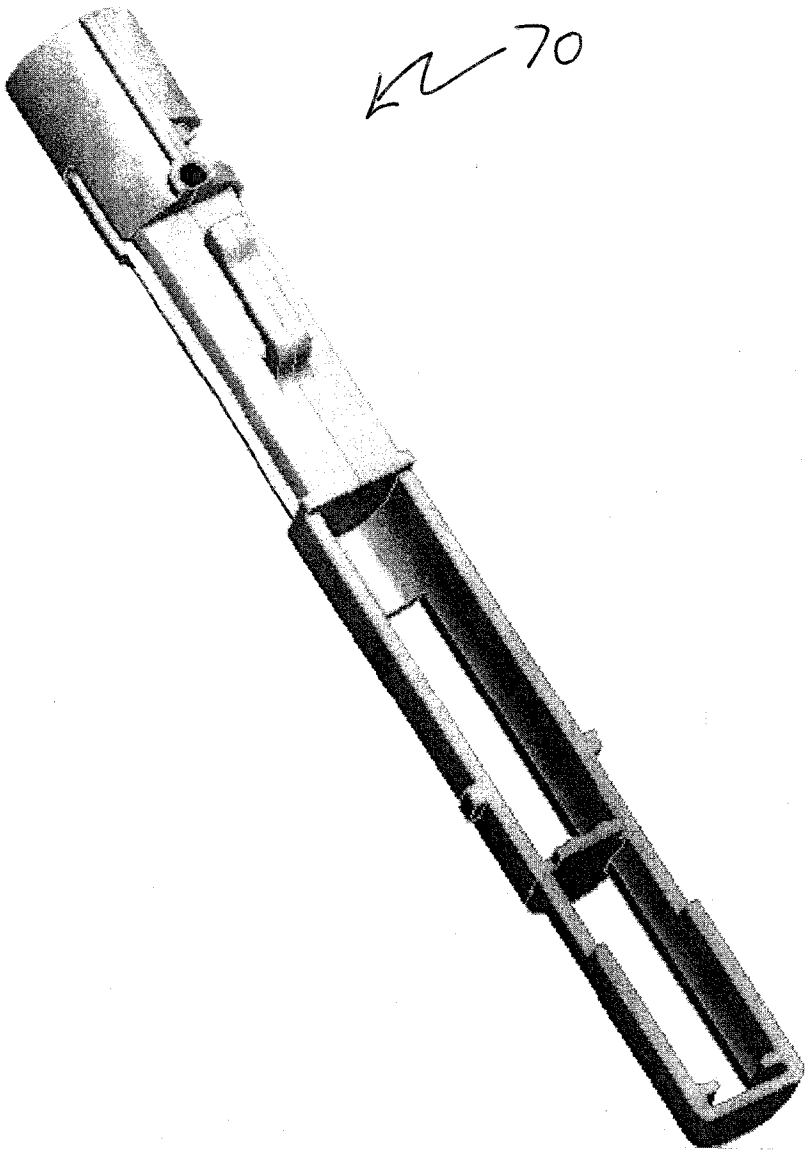
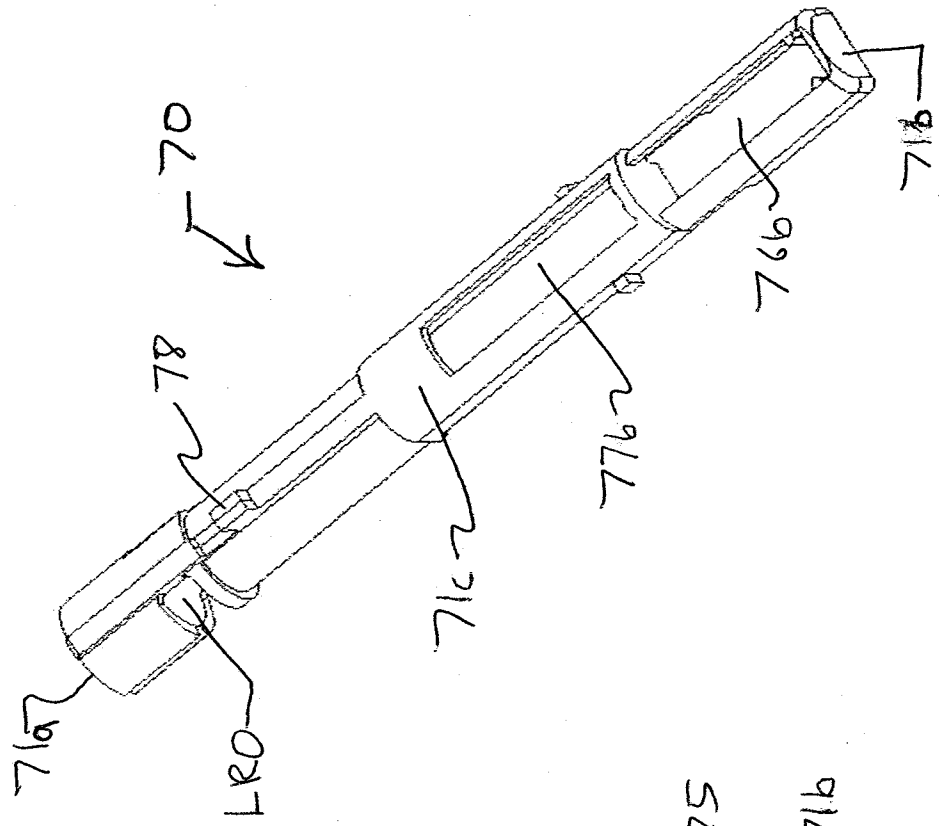


Fig. 40

Fig. 42

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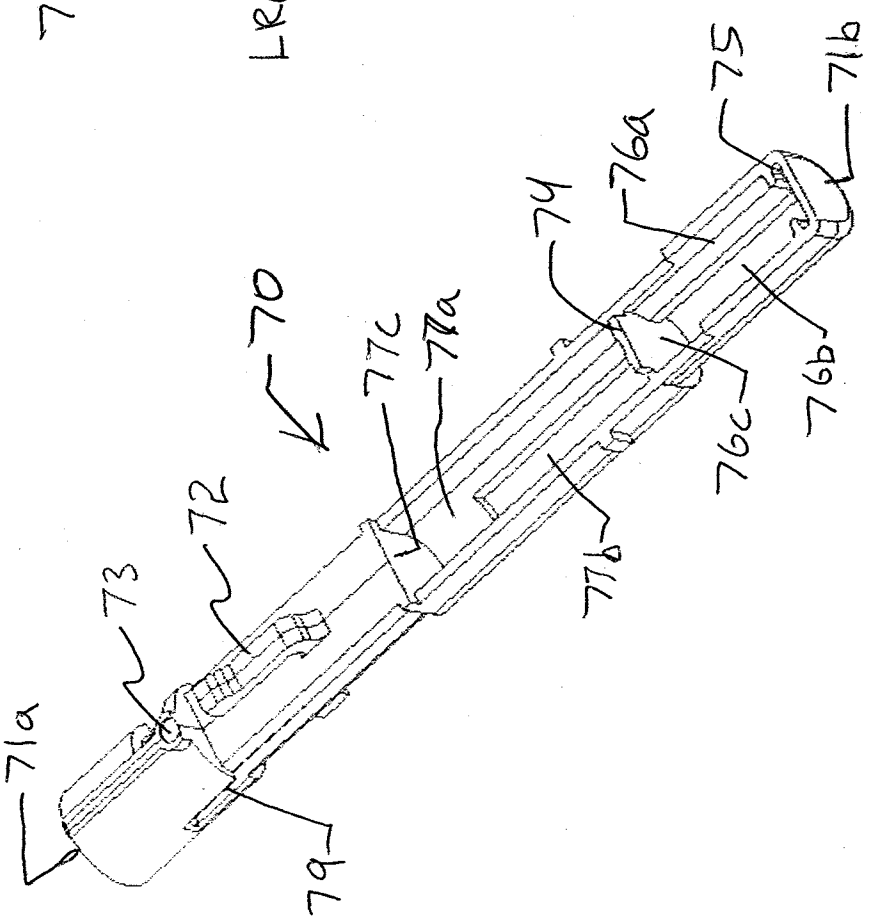
77b
76b
71b
71a
LRO

Fig. 44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76b

Fig. 43

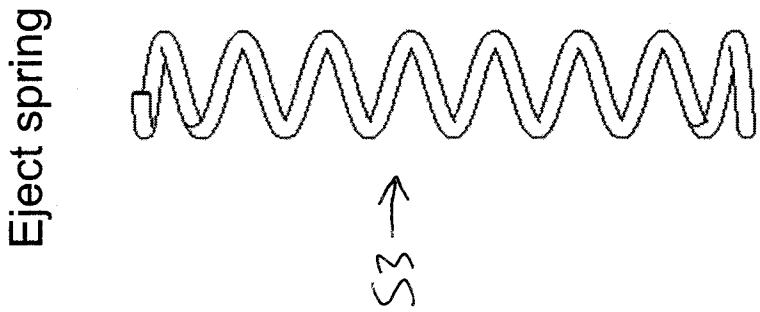

Fig. 47

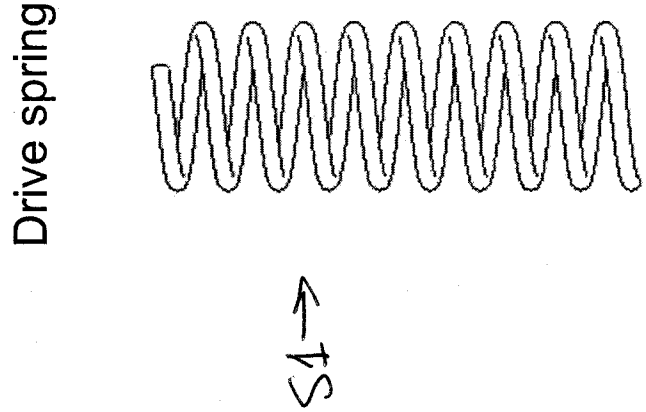

Fig. 46

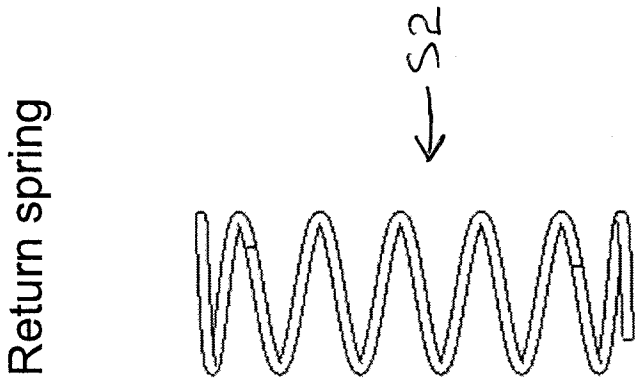

Fig. 45

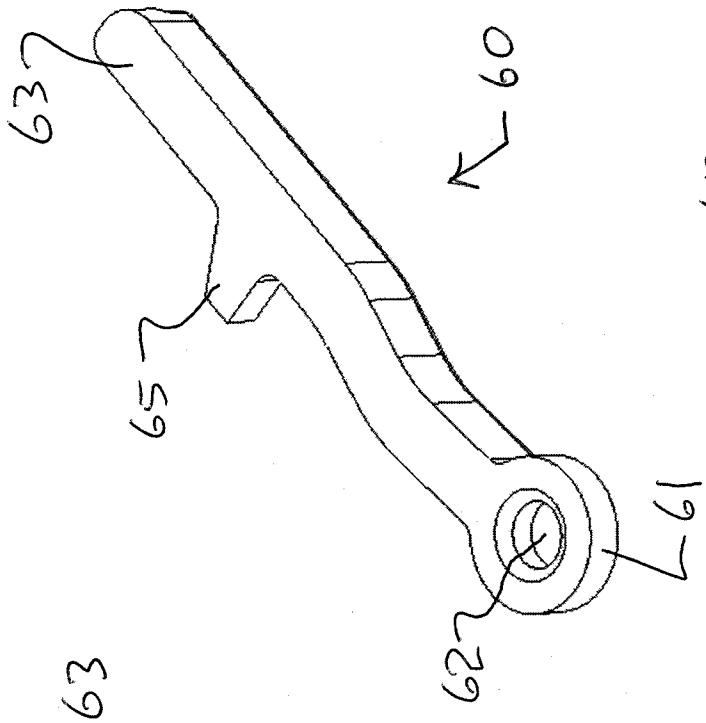

Fig. 49

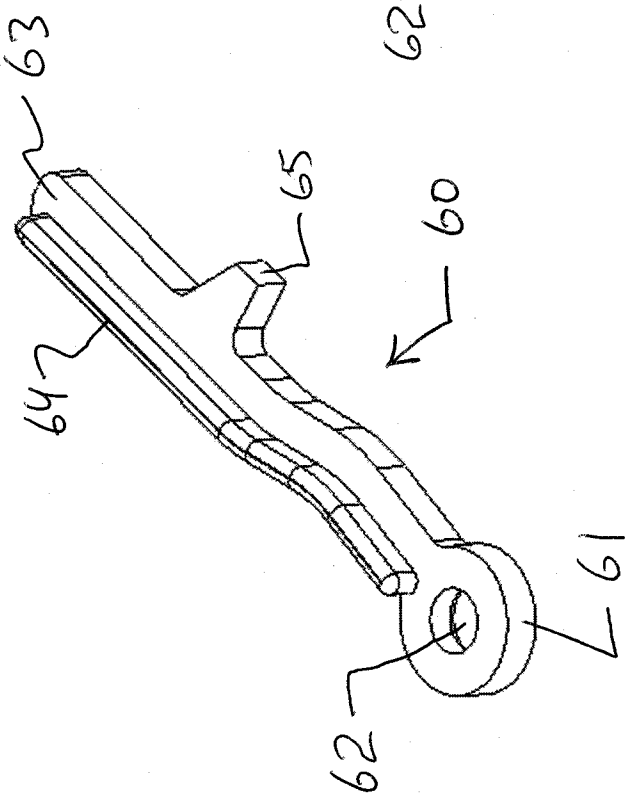

Fig. 48

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2008/067355

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61B 5/15 (2008.04)
USPC - 606/181
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8) - A61B 5/15, 5/151 (2008.04)
USPC - 606/181,182

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PatBase

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2004/0236362 A1 (SHRAGA) 25 November 2004 (25.11.2004) entire document	1-22
Y	US 2007/0083222 A1 (SCHRAGA) 12 April 2007 (12.04.2007) entire document	1-22

☐ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
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"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
24 September 2008	03 OCT 2008

Name and mailing address of the ISA/US	Authorized officer:
Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (April 2005)