

**(12) STANDARD PATENT**  
**(19) AUSTRALIAN PATENT OFFICE**

(11) Application No. **AU 2014202573 B2**

(54) Title  
**Lancet device**

(51) International Patent Classification(s)  
**A61B 17/14** (2006.01)

(21) Application No: **2014202573**

(22) Date of Filing: **2014.05.13**

(43) Publication Date: **2014.06.05**

(43) Publication Journal Date: **2014.06.05**

(44) Accepted Journal Date: **2016.02.25**

(62) Divisional of:  
**2012200142**

(71) Applicant(s)  
**Becton, Dickinson and Company**

(72) Inventor(s)  
**Karbowniczek, Jacek Grzegorz; Rutynowski, Wlodzinierz**

(74) Agent / Attorney  
**FB Rice, Level 23 44 Market Street, Sydney, NSW, 2000**

(56) Related Art  
**EP 1219242**  
**EP 1247489**  
**US 3741197**  
**US 2004/0236362**

**ABSTRACT**

The lancet device includes a housing and a lancet having a puncturing element. The lancet is disposed within the housing and is adapted for axial movement between an initial or pre-actuated position wherein the puncturing element is retained within the housing, and a puncturing position wherein the puncturing element extends through a forward opening in the housing. The lancet device includes a drive spring disposed within the housing for biasing the lancet toward the puncturing position, and a retraction or return spring for returning the lancet to a position within the housing where the puncturing element is disposed within the housing. The retraction spring thereafter maintains engagement with the lancet to assist in preventing the puncturing element from again projecting outward from the forward opening in the housing.



**AUSTRALIA**  
**Patents Act 1990**

**BECTON, DICKINSON AND COMPANY**

**COMPLETE SPECIFICATION**

**STANDARD PATENT**

*Title:*

*Lancet device*

The following statement is a full description of this invention including the best method of performing it known to us:-

## LANCET DEVICE

### BACKGROUND OF THE INVENTION

#### Field of the Invention

[0001] The invention relates generally to medical puncturing devices, commonly referred to as lancets, which are used to take blood samples from patients and, more specifically, to a lancet device that is designed for ease of use with activation achieved during contact of the device in normal use.

#### Description of Related Art

[0002] Lancet devices are used in the medical field for puncturing the skin of a patient to obtain a capillary blood sample from the patient. Certain diseases, such as diabetes, require that the patient's blood be tested on a regular basis to monitor, for example, the patient's blood sugar levels. Additionally, test kits, such as cholesterol test kits, often require a blood sample for analysis. The blood collection procedure usually involves pricking a finger or other suitable body part in order to obtain the blood sample. Typically, the amount of blood needed for such tests is relatively small and a small puncture wound or incision normally provides a sufficient amount of blood for these tests.

[0003] Various lancet devices are commercially available to hospitals, clinics, doctors' offices, and the like, as well as to individual consumers. Such devices typically include a sharp-pointed member such as a needle, or a sharp-edged member such as a blade, that is used to make a quick puncture wound or incision in the patient's skin in order to provide a small outflow of blood. It is often physiologically and psychologically difficult for many people to prick their own finger with a hand-held needle or blade. As a result, lancet devices have evolved into devices that facilitate puncturing or cutting the skin of the patient upon the actuation of a triggering mechanism. In some devices, the needle or blade is kept in a standby position until it is triggered by the user, who may be a medical professional in charge of drawing blood from the patient, or the patient himself or herself. Upon triggering, the needle or blade punctures or cuts the skin of the patient, for example on the finger. Often, a spring is incorporated into the device to provide the "automatic" force necessary to puncture or cut the skin of the patient.

[0004] It is of the utmost importance in the medical field that such medical puncturing devices or lancets are in a sterile condition before use. Today, generally without exception, medical puncturing devices or lancets are manufactured and packaged in a sterilized condition before they are distributed to medical professionals and members of the public who

have a need for such devices. The sterile packaging maintains the sterility of the device, ensuring that the surrounding environment does not contaminate it until use. In addition, it is also of increasing importance that the user or another person does not come into contact with the needle or blade after use of the device. With the concern over blood-borne diseases, medical professionals are required to take great care with medical devices that come into contact with the blood of patients. Thus, an important aspect of lancet design involves preventing the needle or blade of the device from wounding the user or another person after the blood sample is drawn from the patient. Once used, the needle or blade should be shielded to prevent the needle or blade from wounding the user or another person handling the device. Moreover, the lancet device should be disposable to eliminate the chances of disease transmission due to the needle or blade being used on more than one person. In this regard, the lancet device should ideally be designed for one firing, and have safety features to prevent reuse.

**[0005]** Advances have been made in recent years to increase safety in operating and handling used lancet devices. For example, lancet devices are currently available which are single shot devices that feature automatic ejection and retraction of the puncturing or cutting element from and into the device. Examples of such medical puncturing devices are disclosed in United States Patent Nos. 6,432,120; 6,248,120; 5,755,733; and 5,540,709.

**[0006]** United States Patent No. 6,432,120 to Teo discloses a lancet device that includes a lancet holder which contains a spring-loaded lancet structure. The spring-loaded lancet structure includes a single spring that effects the ejection and retraction of a lancet needle upon the triggering of the structure. United States Patent No. 6,248,120 to Wyszogrodzki discloses a lancet device comprised of a housing, a shielding portion, a piston with a puncturing tip, and drive and return springs that eject and retract the piston, respectively, upon the breakage of internal wing elements in the housing. United States Patent No. 5,755,733 to Morita discloses a lancet device that includes a combined holder and lancet structure. The lancet structure includes a lancet member with a puncturing tip and a compressible spring member that causes the lancet member to puncture the skin of a patient upon actuation of a pair of actuating arms.

**[0007]** United States Patent No. 5,540,709 to Ramel discloses a lancet device that includes a housing enclosing a slidable trigger, which is used to trigger a compressed spring that powers a piercing lancet member to pierce the skin of a patient. The housing includes a pair of internal fingers that engage the body of the lancet member, which are then released of engagement with the lancet member body by axial force applied by the user to the slidable

trigger. Other medical puncturing devices or lancets known in the art are disclosed in United States Patent Nos. 4,869,249 and 4,817,603. The devices disclosed in these references include a cap that is used to protect a needle or to keep the needle sterile.

**[0008]** In view of the foregoing, a need generally exists in the medical field for a medical puncturing device that is easy for a user to manipulate and use while ensuring sterility before use and safe and secure disposal after use. Additionally, a need exists in the medical field for a simple, inexpensive, reliable, and disposable medical puncturing device for use in collecting blood samples.

**[0008A]** Any discussion of documents, acts, materials, devices, articles or the like which has been included in the present specification is not to be taken as an admission that any or all of these matters form part of the prior art base or were common general knowledge in the field relevant to the present disclosure as it existed before the priority date of each claim of this application.

**[0008B]** Throughout this specification the word "comprise", or variations such as "comprises" or "comprising", will be understood to imply the inclusion of a stated element, integer or step, or group of elements, integers or steps, but not the exclusion of any other element, integer or step, or group of elements, integers or steps.

### SUMMARY OF THE INVENTION

**[0009]** The present invention is generally directed to a lancet device. The lancet device according to a first embodiment comprises a housing, a shield at least partially disposed within the housing and movably associated therewith, and a lancet disposed in the housing and axially movable through the shield. The lancet comprises a puncturing element, and is adapted for axial movement between an initial position wherein the puncturing element is disposed within the housing and a puncturing position wherein the puncturing element extends through a forward opening in the shield for a puncturing procedure. A drive spring is disposed between a rearward end of the housing and the lancet for biasing the lancet to the puncturing position. The lancet device further comprises an actuator associated with the shield and in interference engagement with the lancet in the initial position. In operation, axial movement of the shield into the housing causes the actuator to move the lancet toward and contact the rearward end of the housing to at least partially compress the drive spring. Upon contact with the rearward end of the housing, further force applied to retract the shield into the housing causes failure of the

interference engagement between the actuator and the lancet thereby releasing the at least partially compressed drive spring and permitting the drive spring to bias the lancet through the shield to the puncturing position. The actuator comprises a shearable element associated with a proximal end of the shield, and the shearable element may comprise at least one breakable shelf or tab providing the interference engagement with the lancet.

**[0010]** The lancet device according to a second embodiment comprises a housing, a shield at least partially disposed within the housing and movably associated therewith, with the shield comprising at least one internal tab, and a lancet disposed in the housing and axially movable through the shield. The lancet comprises a puncturing element, and is adapted for



axial movement between an initial position wherein the puncturing element is disposed within the housing and a puncturing position wherein the puncturing element extends through a forward opening in the shield for a puncturing procedure. The lancet is in interference engagement with the internal tab in the shield in the initial position. A drive spring is disposed between a rearward end of the housing and the lancet for biasing the lancet to the puncturing position. In operation, axial movement of the shield into the housing causes the lancet to move toward and contact the rearward end of the housing due to the interference engagement with the shield internal tab to at least partially compress the drive spring. Upon contact with the rearward end of the housing, further force or movement applied to retract the shield into the housing causes failure of the internal tab removing the interference engagement and releasing the at least partially compressed drive spring to bias the lancet through the shield to the puncturing position. The lancet may comprise a cutting element providing the interference engagement with the internal tab in the initial position of the lancet, and failure of the internal tab may be caused by the cutting element cutting through the internal tab.

**[0011]** The lancet device according to a third embodiment comprises a housing, a shield at least partially disposed within the housing and movably associated therewith, and a lancet disposed in the housing and axially movable through the shield and comprising a puncturing element. The lancet is generally adapted for axial movement between an initial position wherein the puncturing element is disposed within the housing and a puncturing position wherein the puncturing element extends through a forward opening in the shield for a puncturing procedure. A drive spring is disposed between a rearward end of the housing and the lancet for biasing the lancet to the puncturing position. The lancet device further comprises an actuator in interference engagement with the lancet in the initial position and maintains the drive spring in an at least partially compressed state in the initial position of the lancet. The actuator comprises a sleeve portion associated with the housing and at least one elastic element in interference engagement with the lancet. In operation, axial movement of the shield into the housing causes the shield to move the elastic element radially outward from the lancet releasing the interference engagement therewith, and thereby releasing the at least partially compressed drive spring to bias the lancet through the shield to the puncturing position. The sleeve portion and elastic element may be formed integrally and connected, for example, by a living hinge.

**[0012]** The lancet device according to fourth embodiment comprises a housing and a lancet disposed in the housing and axially movable through the housing and comprising a

puncturing element. The lancet is adapted for axial movement between an initial position wherein the puncturing element is disposed within the housing and a puncturing position wherein the puncturing element extends through a front opening in the housing for a puncturing procedure. A drive spring is disposed between a rearward end of the housing and the lancet for biasing the lancet to the puncturing position. The drive spring is held in at least partially compressed state between the rearward end of the housing and the lancet by an interference engagement between the lancet and housing. The lancet device further comprises an actuator pivotally connected to the housing and in contact engagement with the lancet in the initial position for causing release of the drive spring. In operation, movement, typically depression, of the actuator causes pivotal movement thereof into the housing causing at least a portion of the lancet to move downward in the housing until the lancet is released of interference engagement with the housing, thereby releasing the at least partially compressed drive spring to bias the lancet through the housing to the puncturing position. The lancet may comprises at least one outward-extending guide tab and the housing may define an internal guide channel comprising a longitudinal main channel and a generally transverse side channel, such that the interference engagement comprises the guide tab engaging a corner or vertex defined generally at the intersection of the main channel and side channel.

**[0013]** The lancet device according to a fifth embodiment comprises a housing having an internal cam surface at a rearward end thereof, a shield at least partially disposed within the housing and movably associated therewith, and a lancet disposed in the housing and axially movable through the shield and comprising a puncturing element. The lancet is adapted for axial movement between an initial position wherein the puncturing element is disposed within the housing and a puncturing position wherein the puncturing element extends through a forward opening in the shield for a puncturing procedure. A drive spring is disposed between the rearward end of the housing and the lancet for biasing the lancet to the puncturing position. The lancet device further comprises an actuator associated with a proximal end of the shield disposed in the housing and in interference engagement with the lancet in the initial position thereof. In operation, axial movement of the shield into the housing causes the actuator to move the lancet toward the rearward end of the housing to at least partially compress the drive spring while simultaneously interacting with the internal cam surface. Continued interaction with the internal cam surface during the shield axial movement further moves the actuator to a position within the housing where the interference engagement between the actuator and the lancet is released, thereby releasing the at least

partially compressed drive spring and permitting the drive spring to bias the lancet through the shield to the puncturing position. The actuator may comprise a plate member slidably associated with the shield proximal end and defining a keyhole for permitting passage of the lancet therethrough to release the interference engagement.

**[0014]** The lancet device according to a sixth embodiment comprises a housing and a lancet disposed in the housing and axially movable through the housing. The lancet device comprises a puncturing element, and is adapted for axial movement between an initial position wherein the puncturing element is disposed within the housing and a puncturing position wherein the puncturing element extends through a front opening in the housing for a puncturing procedure. A drive spring is disposed between a rearward end of the housing and the lancet for biasing the lancet to the puncturing position. The lancet device further comprises an actuator associated with the housing and in interference engagement with the lancet in the initial position. The interference engagement between actuator and lancet maintains the drive spring in at least a partially compressed state between the rearward end of the housing and the lancet in the initial position. In operation, movement, typically depression, of the actuator into the housing moves the actuator to a position within the housing where the interference engagement between the actuator and the lancet is released, thereby releasing the at least partially compressed drive spring and permitting the drive spring to bias the lancet through the shield to the puncturing position. The actuator may comprise a lever member pivotally connected to the housing and a plate member depending into the housing. The plate member defines a keyhole for permitting passage of the lancet therethrough to release the interference engagement. The lancet device, according to a seventh embodiment, may include the actuator comprising a depressible button associated with the housing and a plate member depending into the housing, with the plate member defining a keyhole for permitting passage of the lancet therethrough to release the interference engagement.

**[0015]** The lancet device according to an eighth embodiment comprises a housing, a lancet disposed in the housing and axially movable through the housing and comprising a puncturing element. The lancet is adapted for axial movement between an initial position wherein the puncturing element is disposed within the housing and a puncturing position wherein the puncturing element extends through a front opening in the housing for a puncturing procedure. A drive spring is disposed between a rearward end of the housing and the lancet for biasing the lancet to the puncturing position. The drive spring is held in at least a partially compressed state between the rearward end of the housing and the lancet by an

interference engagement between the lancet and housing. The lancet device further comprises an actuator connected or optionally integrated pivotally to the housing and adapted to sever the interference engagement between the lancet and housing for causing release of the drive spring. In operation, movement, typically depression, of the actuator causes pivotal movement thereof into the housing until the actuator severs the interference engagement between the lancet and housing thereby releasing the at least partially compressed drive spring to bias the lancet through the housing to the puncturing position. The actuator may comprise a lever member connected pivotally to the housing and comprising a depending cutting edge for severing the interference engagement between the lancet and housing.

[0016] The lancet device according to a further embodiment comprises a housing and a lancet disposed within the housing and comprising a puncturing element. The lancet is adapted for axial movement between an initial, pre-actuated position wherein the puncturing element is retained within the housing and a puncturing position wherein the puncturing element extends through a front opening the housing. A drive spring is disposed between a rearward end of the housing and the lancet for biasing the lancet toward the puncturing position. The lancet device further comprises a retaining hub retaining the lancet in the pre-actuated position. The retaining hub is adapted to retain the lancet against the bias of the drive spring, and comprises a pivotal cam element. The cam element is in interference engagement with the lancet in the pre-actuated position of the lancet. In operation, axial movement of the housing toward the retaining hub causes the cam element to pivot, thereby moving the lancet toward the rearward end of the housing to at least partially compress the drive spring and releasing the cam element from interference engagement with the lancet, permitting the drive spring to drive the lancet through the housing toward the puncturing position. The cam element may define a recess or notch which releases the cam element from the interference engagement with the lancet when the cam element is pivoted to align the recess with an interfering on the lancet.

[0017] The lancet device may further comprise an internal contact within the housing and axial movement of the housing toward the retaining hub causes the internal contact within the housing to pivot the cam element. The cam element may comprise a contact surface for engagement with the internal contact of the housing. The internal contact of the housing may comprise an integrally formed cam surface for cooperating engagement with the contact surface of the cam element. The retaining hub may comprise an annular rim, generally defined by a pair of opposed support members connected by a pair of pivotal cam elements. The cam elements may comprise pivotal shafts connecting the support members.

[0018] The lancet device according to a final embodiment generally comprises a housing including an internal actuation member, a shield at least partially disposed within the housing and movably associated therewith, a lancet disposed in the housing and axially movable through the shield, and a rotation element. The lancet includes a puncturing element and is adapted for axial movement between an initial position wherein the puncturing element is disposed within the housing, and a puncturing position wherein the puncturing element extends through a forward opening in the shield for a puncturing procedure. A drive spring is typically disposed between a rearward end of the housing and the lancet for biasing the lancet to the puncturing position. The lancet is typically in interference engagement with the rotation element in the initial position. In operation, axial movement of the shield into the housing causes the actuation member to rotate the rotation element relative to the lancet to a release position releasing the interference engagement between the lancet and rotation element, thereby permitting the drive spring to bias the lancet through the shield to the puncturing position.

[0019] The rotation element may be associated with the shield such that axial movement of the shield into the housing causes the drive spring to at least partially compress between the housing rearward end and lancet due to the interference engagement between the lancet and rotation element. The rotation element may be associated with a rearward end of the shield disposed in the housing.

[0020] The actuating member may comprise a cam element with a cam surface and the rotation element may comprise a guide plate defining a cam guide recess for receiving the cam element, such that axial movement of the shield into the housing causes the cam surface to engage the cam guide recess and impart rotational motion to the guide plate. The lancet may comprise an actuation tab in interference engagement with the guide plate, and the guide plate may define a clearance slot, such that the interference engagement may be released when the guide plate rotates to the release position where the actuation tab aligns with the clearance slot.

[0021] The actuating member may comprise a cam element with a cam surface and the rotation element may comprise a cam follower, such that axial movement of the shield into the housing causes the cam surface to engage the cam follower and impart rotational motion thereto at least until the cam follower reaches the release position.

[0022] Further details and advantages of the invention will become clear from the following detailed description when read in conjunction with the accompanying drawings.

**BRIEF DESCRIPTION OF THE DRAWINGS**

[0023] FIG. 1 is a longitudinal cross-sectional view of a first embodiment of a lancet device showing the lancet device in an initial, pre-actuated state;

[0024] FIG. 2 is a longitudinal cross-sectional view of the lancet device of FIG. 1 taken along a perpendicular longitudinal axis to the cross-sectional view in FIG. 1;

[0025] FIG. 3 is a longitudinal cross-sectional view of the lancet device of FIG. 1 showing the lancet device in an initial stage of actuation;

[0026] FIG. 4 is a longitudinal cross-sectional view of the lancet device of FIG. 1 showing the lancet device immediately after actuation;

[0027] FIG. 5 is a longitudinal cross-sectional view of the lancet device of FIG. 1 showing the lancet device after actuation with a lancet of device partially exposed for a puncturing procedure;

[0028] FIG. 6 is a longitudinal cross-sectional view of the lancet device of FIG. 1 showing the lancet device in a final state after actuation;

[0029] FIG. 7 is a longitudinal cross-sectional view of a second embodiment of the lancet device showing the lancet device in the initial, pre-actuated state;

[0030] FIG. 8 is a longitudinal cross-sectional view of the lancet device of FIG. 7 taken along a perpendicular longitudinal axis to the cross-sectional view in FIG. 7;

[0031] FIG. 9 is a longitudinal cross-sectional view of the lancet device of FIG. 7 showing the lancet device in the initial stage of actuation;

[0032] FIG. 10 is a longitudinal cross-sectional view of the lancet device of FIG. 7 with the lancet of device removed for viewing the interior of the device;

[0033] FIG. 11 is a longitudinal cross-sectional view of the lancet device of FIG. 7 showing the lancet device after actuation with the lancet of device partially exposed for a puncturing procedure;

[0034] FIG. 12 is a longitudinal cross-sectional view of the lancet device of FIG. 7 showing the lancet device in the final state after actuation;

[0035] FIG. 13 is a longitudinal cross-sectional view of a third embodiment of the lancet device showing the lancet device in the initial, pre-actuated state;

[0036] FIG. 14 is a longitudinal cross-sectional view of the lancet device of FIG. 13 showing the lancet device in the initial stage of actuation;

[0037] FIG. 15 is a longitudinal cross-sectional view of the lancet device of FIG. 13 showing the lancet device in a later stage of actuation;

- [0038] FIG. 16 is a cross-sectional view of the lancet device of FIG. 13 showing the lancet device immediately after actuation;
- [0039] FIG. 17 is a longitudinal cross-sectional view of the lancet device of FIG. 13 showing the lancet device after actuation with the lancet of the device partially exposed for a puncturing procedure;
- [0040] FIG. 18 is a longitudinal cross-sectional view of the lancet device of FIG. 13 showing the lancet device in the final state after actuation;
- [0041] FIG. 19 is a longitudinal cross-sectional view of a fourth embodiment of the lancet device showing the lancet device in the initial, pre-actuated state;
- [0042] FIG. 20 is a longitudinal cross-sectional view of the lancet device of FIG. 19 showing the lancet device in the initial stage of actuation;
- [0043] FIG. 21 is a cross-sectional view of the lancet device of FIG. 19 showing the lancet device immediately after actuation;
- [0044] FIG. 22 is a longitudinal cross-sectional view of the lancet device of FIG. 19 with the lancet of the device removed for viewing the interior of the device;
- [0045] FIG. 23 is a longitudinal cross-sectional view of the lancet device of FIG. 19 showing the lancet device after actuation with the lancet of the device partially exposed for a puncturing procedure;
- [0046] FIG. 24 is a longitudinal cross-sectional view of a fifth embodiment of the lancet device showing the lancet device in the initial, pre-actuated state;
- [0047] FIG. 25 is longitudinal cross-sectional view of the lancet device of FIG. 24 taken along a perpendicular longitudinal axis to the cross-sectional view in FIG. 24;
- [0048] FIG. 26 is a transverse cross-sectional view of the lancet device of FIG. 24 showing the lancet device in the initial stage of actuation with the lancet in an interference engagement within the device;
- [0049] FIG. 27 is a transverse cross-sectional view of the lancet device of FIG. 24 showing the lancet device at the point of actuation with the lancet released of the interference engagement within the device;
- [0050] FIG. 28 is a longitudinal cross-sectional view of the lancet device of FIG. 24 showing the lancet device in the initial stage of actuation
- [0051] FIG. 29 is a longitudinal cross-sectional view of the lancet device of FIG. 24 showing the lancet device at the point of actuation;

[0052] FIG. 30 is a longitudinal cross-sectional view of the lancet device of FIG. 24 showing the lancet device after actuation with the lancet of the device partially exposed for a puncturing procedure;

[0053] FIG. 31 is a longitudinal cross-sectional view of a sixth embodiment of the lancet device showing the lancet device in the initial, pre-actuated state;

[0054] FIG. 32 is a second longitudinal cross-sectional view of the lancet device of FIG. 31 showing the lancet device in the initial, pre-actuated state;

[0055] FIG. 33 is a transverse cross-sectional view of the lancet device of FIG. 31 showing the lancet device in the initial stage of actuation with the lancet in an interference engagement within the device;

[0056] FIG. 34 is a transverse cross-sectional view of the lancet device of FIG. 31 showing the lancet device at the point of actuation with the lancet released of the interference engagement within the device;

[0057] FIG. 35 is a longitudinal cross-sectional view of the lancet device of FIG. 31 showing the lancet device in the initial stage of actuation;

[0058] FIG. 36 is a longitudinal cross-sectional view of the lancet device of FIG. 31 showing the lancet device at the point of actuation;

[0059] FIG. 37 is a longitudinal cross-sectional view of the lancet device of FIG. 31 showing the lancet device after actuation with the lancet moving within the device toward a puncturing position;

[0060] FIG. 38 is a longitudinal cross-sectional view of a seventh embodiment of the lancet device showing the lancet device in the initial, pre-actuated state;

[0061] FIG. 39 is a longitudinal cross-sectional view of the lancet device of FIG. 38 showing the lancet device in the initial stage of actuation with the lancet in an interference engagement within the device;

[0062] FIG. 40 is a transverse cross-sectional view of the lancet device of FIG. 38 showing the lancet device at the point of actuation with the lancet released of the interference engagement within the device;

[0063] FIG. 41 is a longitudinal cross-sectional view of the lancet device of FIG. 38 showing the lancet device after actuation with the lancet moving within the device toward a puncturing position;

[0064] FIG. 42 is a longitudinal cross-sectional view of the lancet device of FIG. 38 showing the lancet device after actuation with the lancet of device in the puncturing position for a puncturing procedure;



- [0065] FIG. 43 is a longitudinal cross-sectional view of the lancet device of FIG. 38 showing the lancet device in the final state after actuation;
- [0066] FIG. 44 is a perspective view of an eighth embodiment of the lancet device;
- [0067] FIG. 45 is a perspective view of the lancet device of FIG. 44 with a sterile cover associated with the internal lancet removed;
- [0068] FIG. 46 is an exploded perspective view of the lancet device of FIG. 44;
- [0069] FIG. 47 is a perspective view of a portion of the lancet device of FIG. 44 showing an actuator, a drive spring, and the lancet of the device;
- [0070] FIG. 48 is a longitudinal cross-sectional view of the lancet device of FIG. 44 showing the lancet device in the initial, pre-actuated state;
- [0071] FIG. 49 is a longitudinal cross-sectional view of the lancet device of FIG. 44 taken along a perpendicular longitudinal axis to the cross-sectional view in FIG. 48;
- [0072] FIG. 50 is a longitudinal cross-sectional view of the lancet device of FIG. 44 showing the lancet device at the point of actuation;
- [0073] FIG. 51 is a longitudinal cross-sectional view of the lancet device of FIG. 44 showing the lancet device after actuation with the lancet of the device partially exposed for a puncturing procedure;
- [0074] FIG. 52 is a longitudinal cross-sectional view of the lancet device of FIG. 44 showing the lancet device in the final state after actuation;
- [0075] FIG. 53 is a perspective view of a further embodiment of the lancet device;
- [0076] FIGS. 54A-54C are bottom, side, and end views, respectively, of a retaining hub used in the lancet device shown in FIG. 53;
- [0077] FIG. 55 is a perspective view of the retaining hub shown in FIGS. 54A-54C;
- [0078] FIG. 56 is a perspective view of a final embodiment of the lancet device;
- [0079] FIG. 57 is a longitudinal cross-sectional view of the lancet device of FIG. 56;
- [0080] FIG. 58 is a transverse cross-sectional view of the lancet device of FIG. 56 taken along line 58-58 in FIG. 57;
- [0081] FIG. 59 is an exploded and partial cross-sectional view of the lancet device of FIG. 56 showing a rear cap, guide plate and shield of the lancet device;
- [0082] FIG. 60 is a perspective view of a lancet used in the lancet device of FIG. 56;
- [0083] FIG. 61 is a perspective view of a rearward portion of the lancet of FIG. 60 showing the lancet associated with the shield and guide plate shown in FIG. 59;
- [0084] FIG. 62 is a side view of the assembled structure shown in FIG. 61 additionally including the rear cap shown in FIG. 59;

[0085] FIG. 64 is a perspective view of a forward end of the shield of the lancet device of FIG. 56;

[0086] FIGS. 65A and 65B are longitudinal and transverse cross-sectional views, respectively, of the lancet device of FIG. 56 showing the lancet device in an initial, pre-actuated state;

[0087] FIGS. 66A and 66B are longitudinal and transverse cross-sectional views, respectively, of the lancet device of FIG. 56 showing the lancet device in an initial stage of actuation; and

[0088] FIGS. 67A and 67B are longitudinal and transverse cross-sectional views, respectively, of the lancet device of FIG. 56 showing the lancet device at the point of actuation.

### DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0089] For purposes of the description hereinafter, spatial orientation terms, if used, shall relate to the embodiment of the invention as it is oriented in the accompanying drawing figures. However, it is to be understood that the invention may assume many alternative variations and embodiments except where expressly specified to the contrary. It is also to be understood that the specific devices and embodiments illustrated in the accompanying drawing figures and described herein are simply exemplary embodiments of the invention, and wherein like elements are designated with like reference numerals and an accompanying alphabetic designation.

[0090] Referring to FIGS. 1-6, a lancet device **10a** according to a first embodiment is generally shown. The lancet device **10a** generally includes a housing **12a**, a shield **14a** movably associated with the housing **12a**, and a lancet **70a** movably disposed in the housing **12a**. As described in greater detail herein, shield **14a** is movably associated with the housing **12a**, and is at least partially disposed within housing **12a**. The shield **14a** typically extends partially outward from the housing **12a**, while the lancet **70a** is contained within housing **12a** and is axially movable through the shield **14a**.

[0091] The housing **12a** is generally in the form of an elongated body, referred to hereinafter as main body **20a**. The main body **20a** has a generally cylindrical and hollow configuration. The main body **20a** has a distal or forward end portion **22a**, and a rear cap **24a** forming a proximal or rearward end portion **26a** of the main body **20a**. The interior of main body **20a** is generally open and comprises an internal cavity or bore **28a**. The internal cavity

**28a** is closed at the rearward end due to the presence of rear cap **24a**, and includes a front opening **30a** defined by a forward end portion **22a** of main body **20a**, and through which shield **14a** extends. Main body **20a** and rear cap **24a** may be integrally formed. Alternatively, main body **20a** and rear cap **24a** may be separate elements that are affixed together to form housing **12a**, which facilitates assembly of lancet device **10a**. As examples, main body **20a** and rear cap **24a** may be affixed together through an appropriate medical grade adhesive, or connected using inter-engaging structures providing a mechanical engagement therebetween, such as a friction-fit or a snap-fit connection. For example, main body **20a** may include an annular rim **32a** defining an annular groove **34a**, and rear cap **24a** may include a mating annular rim **36a** having a mating annular lip **38a** as mating elements. When main body **20a** and rear cap **24a** are connected, annular lip **38a** extends within the rear open end of main body **20a**, with annular lip **38a** snap-fitting over annular rim **32a** and into annular groove **34a** of main body **20**. It should be understood that the arrangement of such elements is merely exemplary and may be reversed, and it is contemplated that other inter-fitting mechanical engagement arrangements may be used to connect the main body **20a** and rear cap **24a**. Main body **20a** further comprises an internal ridge **40a**, typically a perimetrimally-extending ridge **40a** forward of annular groove **34a**, the purpose and function of which will be described herein. Further, main body **20a** of housing **12a** may include a forward rim **42a** formed as part of forward end portion **22a** and which defines front opening **30a**.

[0092] As noted previously, shield **14a** extends outward at least partially from front opening **30a** in the forward end portion **22a** of main body **20a**. Shield **14a** is a generally cylindrical, hollow structure comprising a shield body **50a** having a distal or forward end **52a** and a proximal or rearward end **54a**, and defines an internal cavity or bore **56a** extending therethrough. The forward end **52a** of shield body **50a** defines a partial forward end wall **58a** defining a forward opening **60a**, through which a puncturing element of lancet **70a** extends when lancet device **10a** is actuated by a user as will be discussed in more detail herein. The forward end wall **58a** generally defines a small contact area about forward opening **60a** for contacting an intended puncture area on a patient's body. The reduced contact area may be made smaller (i.e., reduced in surface area) by providing a plurality of peripheral indentations (not shown) formed perimetrimally in shield **14a**. The external surface features of housing **12a** and shield **14a** may be formed in accordance with the ergonomic features and structure disclosed in co-pending application Serial No. 11/123,849, filed November 30, 2004, entitled

“Lancet Device”, and naming Bradley Wilkinson as inventor. The disclosure of the foregoing “Lancet Device” application is incorporated herein by reference thereto.

[0093] The shield **14a** is axially and slidably movable within housing **12a**. The shield **14a** and housing **12a** may be coaxially associated, with the shield **14a** and housing **12a** coaxially disposed around a common Central Axis A. The shield **14a** and housing **12a** may each be generally cylindrically shaped. A shearable element **62a** is further associated with shield **14a**. In particular, shearable element **62a** is disposed at the rearward end **54a** of shield body **50a** and engages a rear rim **63a** of shield body **50a**. Shearable element **62a** comprises an annular sleeve portion **64a** that extends axially in a distal direction along the outer surface of shield body **50a**. The annular sleeve **64a** receives the rearward end **54a** of shield body **50a** so as to be positioned between shield body **50a** and main body **20a** of housing **12a**. In particular, the inner surface of annular sleeve **64a** engages a proximally-extending portion of the outer surface of shield body **50a** at the rearward end **54a** of shield body **50a**, while the outer surface of shearable element **62a** slidably cooperates with the inner surface of main body **20a** of housing **12a**. Shearable element **62a** further typically comprises two opposing and inward-projecting breakable shelves or wings **66a** that engage lancet **70a** as described further herein. While shearable element **62a** is shown with two opposing and inward-extending shelves or wings **66a**, it will be appreciated that only one shelf or wing **66a** is necessary for interference engagement with the lancet **70a** as described herein. Breakable shelves or wings **66a** may comprise a weakened area or score line **67a** for allowing the shelves **66a** to break (i.e., fail) when sufficient downward pressure is applied thereto as discussed herein. Breakable shelves or wings **66a** are generally inwardly radially-extending cantilevers which may be made of a similar or dissimilar material compared to that chosen for shield **14a**.

[0094] Shearable element **62a** is adapted to slide in combination with shield body **50a** in main body **20a** of housing **12a** when axial motion is imparted to shield body **50a**, for example by axially retracting (i.e., inserting) shield body **50a** into main body **20a** to actuate the lancet device **10a** as described herein. For this purpose and to properly engage the rear rim **63a** on the rearward end **54a** of shield body **50a**, shearable element **62a** comprises an abutment recess **68a** defined by sleeve portion **64a** which engages the proximal or rearward end **54a** of shield body **50a**, and rear rim **63a** in particular. Accordingly, any axial motion applied to shield body **50a** to retract (i.e., insert) shield body **50a** into main body **20a** of housing **12a** will be transmitted to shearable element **62a** through the interference engagement of rear rim **63a** in abutment recess **68a**. As a result, shearable element **62a** will

slide within main body **20a** of housing **12a** along with shield body **50a** when axial motion applied thereto for actuating the lancet device **10a**. The captured portion of shield body **50a** may be secured in sleeve portion **64a** of shearable element **62a** so that there is tight engagement between these elements and ensuring that axial motion imparted to shield body **50a** will be transmitted to shearable element **62a**. For example, a medical grade adhesive or mechanical locking engagement may be provided between the inner surface of sleeve portion **64a** and the captured portion (i.e., outer surface) of shield body **50a** at the rearward end **54a** of shield body **50a** to ensure that these elements are secured together and move as a unit in main body **20a** of housing **12a**. Forward rim **42a** of main body **20a** of housing **12a** is formed to provide an interference engagement with the distal end of sleeve portion **64a** of shearable element **62a** to prevent shearable element **62a** and, consequently, shield body **50a** from axially sliding completely out of housing **12a** through front opening **30a**.

[0095] Lancet device **10a** further comprises a lancet **70a** disposed within the housing **12a**, and extending into shield **14a**. Lancet **70a** includes a puncturing element shown in the form of a lancet **72a**. Lancet **72a** comprises a puncturing end **74a** at the forward end thereof. Lancet **70a** is adapted for axial movement through the internal cavity **56a** of shield body **50a** between an initial position, wherein the puncturing end **74a** is disposed within shield body **50a** to a puncturing position wherein the puncturing end **74a** extends beyond the forward opening **60a** of shield body **50a** a sufficient distance to cause a puncture wound in a patient's body. Further details regarding the operation of lancet device **10a** and lancet **70a** are provided hereinafter.

[0096] The puncturing end **74a** of lancet **72a** is adapted for puncturing the skin of a patient, and may be in the form of a pointed end, needle tip, blade edge, and the like. Puncturing end **74a** may include a preferred alignment orientation, such as with a pointed end or a blade aligned in a specific orientation. In such an orientation, shield body **50a** and/or main body **20a** of housing **12a** may include target indicia corresponding to the alignment orientation of puncturing end **74a**. Indentations (not shown) in the shield body **50a** and/or indentations (not shown) in main body **20a** may function as such an alignment orientation, as described in co-pending Application Serial No. 11/123,849, previously incorporated by reference.

[0097] Lancet **70a** further includes a carrier body **76a** supporting lancet **72a** at the rearward end thereof. The carrier body **76a** and shield body **50a** may include corresponding guiding surfaces for guiding the movement of lancet **70a** in shield body **50a**. For example, carrier body **76a** may include guide tabs **78a** on an external surface thereof, with shield body

**50a** defining corresponding guide channels **80a** extending longitudinally along an inner surface thereof for accommodating guide tabs **78a** slidably therein. The carrier body **76** may include a pair of guide tabs **78a** on opposing lateral sides thereof as illustrated, or a single guide tab **78a**, and shield body **50a** may include a corresponding pair of guide channels **80a** extending along opposing inner surfaces thereof corresponding to each of the guide tabs **78a**, or a single corresponding guide channel **80a**. It is contemplated that the arrangement of the guide tabs and channels **78a**, **80a** may be reversed, and multiple guide tabs-guide channels **78a**, **80a** (i.e., three or more) may also be used. The guide tabs **78a** and guide channels **80a** ensure that lancet **70a** is properly aligned within shield body **50a**, and guides the sliding axial movement of lancet **70a** within shield body **50a** and, further, may be used to prevent or resist rotational movement of carrier body **76a** in shield body **50a**. A distal facing surface **82a** on guide tabs **78a** engages shelves or wings **66a** on shearable element **62a** in the initial or pre-actuated state of lancet device **10a** until the shelves or wings **66a** are broken to release lancet **70a**. The carrier body **76a** further comprises a proximal or rearward end spring guide **86a** and a distal or forward end spring guide **88a** for engaging a drive spring and retraction spring, respectively, of lancet device **10a** as described herein. Spring guides **86a**, **88a** may be formed integral with the carrier body **76a** or be provided as distinct, separate elements and secured to the body of carrier body **76a** by means customary in the medical field as, for example, with medical grade adhesive or direct mechanical attachment.

[0098] Movement of the lancet **70a** through the lancet device **10a** is achieved through a biasing force provided by a drive spring **92a**. Drive spring **92a** is adapted to exert a biasing force against lancet **70a** to drive lancet **70a** through the lancet device **10a** toward the puncturing position, and is disposed between the rearward end of the housing **12a** and the lancet **70a**. Rear cap **24a** may include structure for alignment of and/or for maintaining drive spring **92a** in the proper orientation on rear cap **24a**. For example, rear cap **24a** may include an internal alignment structure (not shown) for correctly positioning the drive spring **92a**. The lancet **70a**, as indicated previously, includes proximal spring guide **86a** which engages the opposite end of drive spring **92a** in the initial or pre-actuated state of lancet device **10a**. In the initial state of lancet device **10a**, drive spring **92a** extends between rear cap **24a** and distal spring guide **86a** of carrier body **76a**. When the lancet **70a** is in the initial, pre-actuated state, drive spring **92a** is in a substantially unloaded, relaxed condition and exerts little to no biasing force on lancet **70a**. Upon compressing or “loading” the drive spring **92a**, the lancet device **10a** is placed into an armed or loaded state ready for a puncturing procedure as described in detail herein.

[0099] A retraction or return spring **94a** may further be provided at the forward or distal end of the lancet device **10a**, for retracting the lancet **70a** within the shield body **50a** after the lancet **70a** has moved distally to the puncturing position wherein the puncturing element **74a** extends outward from the distal or forward end **54a** of shield body **50a** a sufficient distance to cause a puncture wound in the patient. Retraction spring **94a** is adapted to be engaged by distal spring guide **88a** extending forward from carrier body **76a** during the forward movement of lancet **70a**, as described herein. The forward or distal end wall **58a** of shield body **50a** further comprises an axially rearward, or proximally-extending internal sleeve **96a** which defines a distal end pocket **98** for receiving retraction spring **94a**. The retraction spring **94a** is disposed in distal end pocket **98a** throughout the operation sequence of lancet device **10a** in a puncturing procedure. The retraction spring **94a** may be secured in distal end pocket **98a** through use of a medical grade adhesive or by mechanically securing retraction spring **94a** in distal end pocket **98a**. The drive and retraction springs **92a**, **94a** are typically compression springs capable of storing potential energy when in a compressed state.

[00100] Lancet device **10a** may further include a protective tab or cover **100a** for protectively covering the forward end of the lancet **70a** and, in particular, the puncturing end **74a** of lancet **72a**. The tab or cover **100a** protectively covers puncturing end **74a** to maintain sterility thereof prior to use. The tab or cover **100a** is typically a relatively thin and elongated structure that extends from carrier body **76a** through the forward opening **60a** in shield body **50a** for grasping by a user of the lancet device **10a**. Tab or cover **100a** may be integrally formed with the body of carrier body **76a**, for example, by being integrally formed with carrier body **76a** during a plastic molding process. The connection between tab or cover **100a** and carrier body **76a** may include a weakened area in the form of a perimeter groove or score line, along which the tab or cover **100a** is intended to break to remove the cover **100a** from carrier body **76a**. The tab or cover **100a**, as depicted, extends forward from distal spring guide **88a** of carrier body **76a**. Tab or cover **100a** is sized to extend axially through retraction spring **94a**. Various configurations of the tab or cover **100a** are described in co-pending Application Serial No. 11/123,849, previously incorporated by reference.

[00101] The respective elements of the lancet device **10a** are all typically formed of molded plastic material, such as a medical grade plastic material. The lancet **72a** may be constructed of any suitable material adapted for puncturing the skin, and is typically a surgical grade metal such as stainless steel.

[00102] Use and actuation of lancet device **10a** will now be described with continued reference to FIGS. 1-6. Lancet device **10a** is typically initially provided with cover **100a**

extending distally from carrier body 76a, and through forward opening 60a in the forward end wall 58a of shield body 50a. In the initial, unarmed state of lancet device 10a, the drive spring 92a is substantially uncompressed (i.e., unloaded) and in a relaxed state. Drive spring 92a extends from the inner side of rear cap 24a to the carrier body 76a and, more particularly, is disposed about proximal spring guide 86a of carrier body 76a. To use the lancet device 10a in a puncturing procedure, the drive spring 92a must be compressed and placed into a compressed, armed state to provide the biasing force needed to move the lancet 70a through housing 12a and shield 14a. Further, in the initial state, the drive spring 92a acts on spring guide 86a substantially only to position lancet 70a within main body 20a of housing 12a. More particularly, drive spring 92a positions carrier body 76a at a relatively fixed and stationary position within main body 20a of housing 12a, wherein the lancet 70a occupies a generally fixed position relative to main body 20a of housing 12a and shield body 50a of shield 14a. Further, drive spring 92a acting on spring guide 86a of carrier body 76a positions the carrier body 76a such that guide tabs 78a extending laterally from carrier body 76a contact cantilevered shelves or wings 66a on shearable element 62a, which further serves to position shearable element 62a and shield body 50a at a substantially fixed position relative to main body 20a. In particular, the drive spring 92a acts on carrier body 76a to position carrier body 76a such that the distal surface 82a on guide tabs 86a is in interference engagement with shelves 66a, and positions the shearable element 62a and shield body 50a at a generally fixed position relative to main body 20a. Accordingly, until the user is ready to use the lancet device 10a, shearable element 62a and shield body 50a are kept at a substantially constant relative position with respect to main body 20a.

[00103] To use the lancet device 10a, the user grasps opposing sides of housing 12a, such as between a finger and thumb, and removes breakable cover 100a. Cover 100a is removed typically by moving cover 100a in a combined twisting and pulling motion in forward opening 60a defined in forward end wall 58a of shield body 50a to break the frangible connection with carrier body 76a. Once the frangible connection is broken, the cover 100a may be removed through the forward opening 60a. The forward end wall 58a of shield body 50a may then be placed in contact with a location on the patient's body where it is desired to cause a puncture injury to initiate blood flow. If provided, target indicia may be aligned with the desired location of puncture.

[00104] Once placed against the body, the user exerts a downwardly directed force on main body 20a of housing 12a forcing shield body 50a of shield 14a to retract (i.e., depress) into housing 12a. In particular, the user applies a downward directed force in the direction of



Arrow **X**, thereby applying a force against the user's body (i.e., skin surface). Such force establishes an opposing force on forward end wall **58a** of shield body **50a** causing shield body **50a** to retract axially and proximally within main body **20a** of housing **12a**. As shield body **50a** retracts into main body **20a**, rearward end **54a** of shield body **50a** moves proximally (i.e., rearward) toward rear cap **24a**. The interference engagement between abutment recess **68a** on shearable element **62a** and the rear rim **63a** at the rearward end **54a** of shield body **50a** causes shearable element **62a** to move in combination with shield body **50a** toward rear cap **24a**. Substantially simultaneously, the interference engagement between guide tabs **78a** and shelves or wings **66a** begins to exert compressive pressure or force on drive spring **92a**. In particular, as the user applies downward force on housing **12a**, shield body **50a** and shearable element **62a** move rearward and transmit the opposing force to drive spring **92a** through the interference engagement between distal end surface **82a** on guide tabs **78a** and shelves **66a**, thereby beginning to compress drive spring **92a** between rear cap **24a** and carrier body **76a**.

[00105] As the entire lancet **70a** continues to move rearward, the interference engagement between guide tabs **78a** and shelves **66a** compresses drive spring **92a** between rear cap **24a** and carrier body **76a** and, more particularly, between proximal spring guide **86a** and rear cap **24a**. While the shelves or wings **66a** are intentionally formed to be broken (i.e., frangible), the shelves **66a** are formed with sufficient strength to withstand the force required to axially compress drive spring **92a** between proximal spring guide **86a** and rear cap **24a** a pre-selected distance without breaking. Further downward movement of main body **20a** of housing **12a** eventually causes the proximal spring guide **86a** to contact or "bottom out" against the inner side of rear cap **24a**. At this point, drive spring **92a** substantially reaches its maximum compression between proximal spring guide **86a** and rear cap **24a** and the lancet device **10a** is now "armed" or "loaded" sufficiently to carry out a puncturing procedure. Optionally, spring guide **86a** does not need to contact or "bottom out" against the inner side of rear cap **24a**, and drive spring **92a** may have sufficient stored potential energy to carry out the actuation of lancet device **10a**.

[00106] Once the proximal spring guide **86a** contacts the inner side of rear cap **24a**, continued downward force applied to main body **20a** of housing **12a** is applied entirely to breakable shelves or wings **66a** through the interference engagement with guide tabs **78a**. In particular, once the proximal spring guide **86a** contacts rear cap **24a**, the user's entire downward applied force is transmitted from main body **20a** (i.e., rear cap **24a**) to carrier body **76a** and, accordingly, guide tabs **78a**. The interference engagement between guide tabs **78a**

and shelves **66a** focuses the downward applied force on the shelves **66a**, which will cause the shelves **66a** to yield, shear, or break (i.e., fail) in a distal or forward direction at weakened area **67a** and into internal cavity **56a** of shield body **50a**. At the moment the shelves or wings **66a** break, the restraining or compression force previously applied to drive spring **92a** due to the interference engagement between guide tabs **78a** and shelves **66a** is released, releasing the stored potential energy in drive spring **92a** to allow the drive spring **92a** to move lancet **70a** forward in shield body **50a**. Additionally, with the interference engagement broken between the guide tabs **78a** and shelves **66a** removed, the shearable element **62a** and shield body **50a** are free to retract rearward to engage annular rim **36a** on rear cap **24a** where their further rearward movement thereof is halted. As the shearable element **62a** and shield body **50a** move toward annular rim **36a**, shearable element **62a** rides over top of annular ridge **40a** on the inner surface of main body **20a** of housing **12a**. The engagement of shearable element **62a** with annular ridge **40a** increases the frictional engagement between the shearable element **62a** and main body **20a** of housing **12a**, thereby substantially fixing the position of shearable element **62a** and shield body **50a** relative to main body **20a** and inhibiting the shield body **50a** from moving forward again in main body **20a**. The frictional engagement between the outer surface of shearable element **62a** and annular ridge **40a** operates substantially as a frictional lock or brake to substantially prevent forward movement of shield body **50a** in main body **20a** after the shearable element **62a** and shield body **50a** retract fully into main body **20a** and engage rear cap **24a**.

[00107] With the stored potential energy in compressed drive spring **92a** released, the drive spring **92a** biases the lancet **70a** away from rear cap **24a** and through internal cavity **56a** in shield body **50a**. In particular, with the interference engagement between guide tabs **78a** and shelves **66a** removed, the biasing force of drive spring **92a** propels lancet **70a** downward and distally away from the rear cap **24a** axially through main body **20a** of housing **12a** and shield body **50a** of shield **14a**. During such movement, corresponding guide tabs **78a** and guide channels **80a** guide lancet **70a** axially through shield body **50a**. The biasing force acting on lancet **70a** is preferably sufficient to cause the puncturing end **74a** of lancet **72a** to project a sufficient distance and with sufficient kinetic energy from the forward opening **60a** in shield body **50a** to cause a puncture wound in the desired location on a patient's body. Moreover, during the propelling movement of lancet **70a**, proximal spring guide **86a** on carrier body **76a** of lancet **70a** releases from drive spring **92a** which remains connected to rear cap **24a**.

[00108] Further, as the lancet **70a** moves forward in the propelling movement, distal spring guide **88a** engages the rearward end of retraction spring **94a**. The biasing force provided by drive spring **92a** is at least in part applied to retraction spring **94a** by engagement of distal spring guide **88a** with the rearward end of retraction spring **94a** which causes the retraction spring **94a** to compress toward distal end pocket **98a**. The retraction spring **94a** is designed such that it may be compressed in whole or in part by the biasing force of drive spring **92a** propelling lancet **70a**, but still permits puncturing end **74a** of lancet **72a** to extend through forward opening **60a** in shield body **50a** a sufficient distance and with sufficient force to puncture the skin of the patient and initiate blood flow. Distal spring guide **88a** is sized to provide an abutment surface for abutting against internal sleeve **96a** supporting retraction spring **94a** to prevent lancet **70a** from axial movement entirely out of shield body **50a** through forward or front opening **60a**.

[00109] As indicated previously, retraction spring **94a** is typically a compression spring and will have sufficient resilience to return to a relaxed, unloaded state within shield body **50a** after the lancet **70a** extends to the puncturing position. Accordingly, once the retraction spring **94a** is compressed it will provide a return biasing force on the lancet **70a** by engagement with the distal spring guide **88a** on carrier body **76a**. The retraction spring **94a** thereby acts between the forward end wall **58a** of the shield body **50a** and distal spring guide **88a** on carrier body **76a** to cause sufficient or complete retraction of the lancet **70a** into shield body **50a**. In particular, retraction spring **94a** applies a return biasing force that retracts the puncturing end **74a** of lancet **72a** entirely within shield body **50a**. Moreover, as the retraction spring **94a** returns to a relaxed or unloaded state within shield body **50a**, the lancet **70a** is returned to a static position within shield body **50a**, wherein lancet **70a** is disposed at a relatively fixed and stationary position within shield body **50a**. Once retraction spring **94a** returns to a relaxed or uncompressed state, the retraction spring **94a** maintains the lancet **70a** disposed within the shield body **50a** with puncturing end **74a** shielded within shield body **50a**, and preventing further movement of lancet **70a** to the puncturing position. The lancet device **10a** is therefore safely protected from re-use and may be properly discarded, such as in an appropriate medical waste container.

[00110] Referring to FIGS. 7-12, a second embodiment of a lancet device **10b** is generally illustrated, and comprises the same basic components as lancet device **10a** described previously. Generally, lancet device **10b** comprises a housing **12b**, a shield **14b** movably associated with the housing **12b**, and a lancet **70b** movably disposed in housing **12a** and movable through shield **14b**. As the foregoing basic components of lancet device **10b** are

substantially similar to the corresponding components of lancet device **10a**, only distinct differences between these components will be discussed herein, along with the use and sequence of operation of lancet device **10b**.

[00111] In contrast to lancet device **10a**, lancet device **10b** does not comprise a structure corresponding to shearable element **62a** discussed previously. Lancet device **10b** comprises the shield **14a** having a shield body **50b** with a rear ledge or rim **102** at shield proximal end **54b**. The rear ledge or rim **102** is adapted for interference engagement with forward rim **42b** at the forward end portion **22b** of main body **20a** of housing **12a**. The interference engagement of rear ledge **102** with forward rim **42b** is provided to prevent the shield body **50b** from axially sliding completely out of housing **12b** through front opening **30b** defined in forward rim **42b** prior to actuating lancet device **10b**. Rear rim **102** is sized such that it may contact and slidably engage the inner surface of main body **20b** when shield body **50b** is retracted (i.e., depressed) into main body **20b**, as will occur when the lancet device **10b** is actuated by a user.

[00112] A further difference over lancet device **10a** discussed previously lies in the interfering structure between lancet **70b** and shield **14b** used to place lancet device **10b** into an armed or loaded state, and thereafter cause actuation of lancet device **10b**. In lancet device **10b**, shield body **50b** comprises inward-extending shelves, wings, or internal tabs **104**, which take the place of breakable shelves or wings **66a** on shearable element **62a** in lancet device **10a**. The internal tabs **104** are desirably formed integrally with the shield body **50b**, but may also be part of an additional, separate structure associated with shield body **62a**, for example associated with rear rim **102** and extending into central cavity or bore **56b** of shield body **50b**. While shield body **50b** is shown with two opposing and inward-extending internal tabs **104**, it will be appreciated that only one internal tab **104** is necessary for engagement with the lancet **70b** in a similar manner to that described previously in connection with the breakable shelves or wings **66a** on shearable element **62a**.

[00113] In lancet device **10a**, guide tabs **78a** form the structure on lancet **70a** for an interference engagement with breakable shelves or wings **66a**, which initially just contact shelves **66a** under the position effect of drive spring **92a** in the initial or pre-actuated state of lancet device **10a**. In lancet device **10b**, guide tabs **78b** are further provided or formed with cutting elements **106** which may be cutting blades, edges, and the like. Cutting elements **106** may be formed integrally with guide tabs **78b** or, alternatively, be separate cutting structures secured to guide tabs **78b** by means customary in the medical device field, such as direct mechanical or adhesive attachment. The cutting elements **106** are adapted to cut, shear, or

plastically deform internal tabs **104** in the internal cavity **56b** of shield body **50b** during actuation of lancet device **10b** to permit movement of lancet **70b** through shield body **50b**, and thereby conduct a puncturing procedure. Other than the foregoing structural differences, lancet device **10b** is substantially similar in all other respects to the structure of lancet device **10a** described previously.

[00114] With continued reference to FIGS. 7-12, use and operation of lancet device **10b** will now be discussed. Prior to use, cover **100b** extending distally from carrier body **76b** is removed by breaking the frangible connection with carrier body **76b** in the manner described previously and withdrawing cover **100b** from forward opening **60b** in forward end wall **58b** of shield body **50b**. The forward end wall **58b** of shield body **50b** may then be placed in contact with a target location on a patient's body. In the initial state of lancet device **10b**, the drive spring **92b** is substantially uncompressed (i.e., unloaded) and in a relaxed state. Drive spring **92b** extends from proximal spring guide **86a** of carrier body **76a** to rear cap **24b**. As discussed previously, in the initial state of lancet device **10b**, drive spring **92a** is in a relaxed condition and acts on spring guide **86b** substantially to position lancet **70b** at a stationary position within main body **20b** of housing **12a**, wherein the lancet **70b** occupies a generally fixed position relative to main body **20b**. Additionally, drive spring **92b** acts on spring guide **86b** on carrier body **76b** to position carrier body **70a** in main body **20b** such that guide tabs **78b** and more particularly, cutting elements **106** are in interference engagement with tabs or shelves **104** in the internal cavity **56b** of shield body **50b**. The interference engagement between cutting elements **106** and internal tabs **104** further operates to place shield body **50b** at a generally fixed and stationary position relative to main body **20b**. Accordingly, until the user is ready to use lancet device **10b**, shield body **50b** is kept substantially at a generally fixed and stationary position relative to main body **20a** by virtue of the interference engagement between guide tabs **78b** and internal tabs **104** in shield body **50b**.

[00115] To use the lancet device **10b**, the user grasps opposing sides of housing **12b** and exerts downwardly directed force on main body **20**. This force causes an opposing force on forward end wall **58b** of shield body **50b**, causing shield body **50b** to retract axially within main body **20a**. As shield body **50b** retracts into main body **20b**, rearward end **54a** of shield body **50a** moves proximally (i.e., rearward) toward rear cap **24b**. Due to the interference engagement between guide tabs **78b** and internal tabs or shelves **104** and, more particularly, between cutting elements **106** on guide tabs **78b** and internal tabs or shelves **104**, lancet **70b** also moves rearwardly toward rear cap **24b**. As the shield body **50b** moves rearward, the opposing force is applied to drive spring **92b** through the interference engagement between

cutting elements **106** on guide tabs **78a** and internal tabs or shelves **104**, thereby compressing drive spring **92b** between rear cap **24b** and carrier body **76b**. While internal tabs **104** are intended to cut-through or plastically deformed by cutting elements **106**, they are formed with sufficient strength to withstand being cut-through or sheared-off by cutting elements **106** under the opposing force required to axially compress drive spring **92b** between proximal spring guide **86b** and rear cap **24b**. In other words, internal tabs or shelves **104** are formed to withstand the force required to compress drive spring **92b** a predetermined distance prior to the desired point of triggering. Further downward movement of housing **12b** eventually causes proximal spring guide **86b** to contact the inner side of rear cap **24a**. At this point, drive spring **92ba** substantially reaches its maximum compression with a maximum level of stored potential energy. Lancet device **10b** is now in an armed or loaded state sufficient to carry out a puncturing procedure.

[00116] Once the proximal spring guide **86b** contacts rear cap **24b**, the downward force applied to main body **20b** of housing **12b** is applied entirely to the interference engagement between cutting elements **106** and internal tabs **104**. In particular, once proximal spring guide **86b** contacts rear cap **24b**, the user's entire downward applied force is transmitted from main body **20b** (i.e., rear cap **24b**) to carrier body **76b** and, accordingly, guide tabs **78b** and cutting elements **106**. The downward cutting force on the internal tabs **104** is now sufficient to cut-through or plastically deform internal tabs **104**. At the moment the internal tabs **104** are cut-through or plastically deformed, the opposing force applied to compress drive spring **92b** is released, thereby allowing drive spring **92b** to move lancet **70b** forward in shield **14b**. Additionally, with the interference engagement between guide tabs **78b** and internal tabs **104** removed, shield body **50b** is able to retract further rearward under the downward force still typically applied by the user to housing **12b**. The shield body **50b** ultimately moves rearward to a position engaging annular rim **36b** on rear cap **24b** where further rearward movement is halted. As the shield body **50b** moves toward annular rim **36b** on rear cap **24b**, rear rim **102** on the rearward end **54b** of shield body **50b** rides over top of annular ridge **40b**. The annular ridge **40b** thereafter forms a locking structure to inhibit or prevent subsequent forward movement of shield **50b**.

[00117] With the potential energy stored in drive spring **92b** by compression thereof released, the drive spring **92b** biases lancet **70b** away from rear cap **24b** and through shield body **50b**. During such propelling movement, the corresponding guide tabs **78b** and guide channels **80b** guide lancet **70b** axially through shield body **50b**. The biasing force applied to lancet **70a** is preferably sufficient to cause the puncturing end **74b** of lancet **72b** to project a

sufficient distance and with sufficient force from the forward opening **60b** in shield body **50b** to cause a puncture wound at the target location on the patient's body. Moreover, during the propelling movement of lancet **70b**, proximal spring guide **86b** on carrier body **76b** releases from drive spring **92b** which remains connected to rear cap **24b**. Internal sleeve **96b** at the forward end wall **58b** defines a distal stop for engaging distal spring guide **88b** and prevents lancet **70b** from axial movement entirely out of shield body **50b** through forward opening **60b**.

[00118] As the lancet **70b** moves forward in the propelling movement, distal spring guide **88b** engages retraction spring **94b**. The biasing force applied to lancet **70b** by drive spring **92b** is at least in part applied to retraction spring **94b** by engagement of distal spring guide **88b** with retraction spring **94b**, which causes the retraction spring **94b** to compress toward distal end pocket **98b**. The retraction spring **94a** permits puncturing end **74b** of lancet **72b** to extend through forward opening **60b** in shield body **50b** a sufficient distance and with sufficient kinetic energy to puncture the skin of the patient and initiate blood flow, and thereafter return lancet **70b** to a substantially fixed and stationary position within shield **14b**. In particular, as the retraction spring **94b** returns to a relaxed or unloaded state within shield body **50b**, the lancet **70a** is retracted in shield **14b** and returned to a substantially fixed and stationary positioned within shield body **14b**. Thereafter, the engagement of retraction spring **94b** with distal spring guide **88b** maintains the lancet **70b** at a generally fixed and stationary position within shield body **50b**. This maintains puncturing end **74b** shielded within shield body **50b**, and prevents further movement of lancet **70b** to the puncturing position.

[00119] Referring to FIGS. 13-18, a third embodiment of a lancet device **10c** is generally illustrated, and comprises the same basic components as lancet devices **10a**, **10b** described previously. Generally, lancet device **10c** comprises a housing **12c**, a shield **14c** movably associated with the housing **12c**, and a lancet **70c** movably disposed in housing **12c**. As the foregoing basic components of lancet device **10c** are substantially similar to the corresponding components of lancet devices **10a**, **10b** only distinct differences between these components will be discussed herein, along with the general use and sequence of operation of lancet device **10c**.

[00120] In lancet devices **10a**, **10b**, lancets **70a**, **70b** are initially positioned at substantially fixed and stationary positions in housings **12a**, **12b** by drive springs **92a**, **92b** in the initial, pre-actuated states of these devices. In lancet devices **10a**, **10b**, drive springs **92a**, **92b** are initially in a relaxed, unloaded condition and act upon lancets **70a**, **70b** to position lancets **70a**, **70b** relative to housings **12a**, **12b**. Lancet devices **10a**, **10b** are only placed in an armed

or loaded state when shields **14a**, **14b** are retracted (i.e., depressed) into housings **12a**, **12b** under the force applied by a user, which in turn causes lancets **70a**, **70b** to act upon drive springs **92a**, **92b** and compress and load the respective drive springs **92a**, **92b** with potential energy.

[00121] Lancet device **10c** is initially provided in an armed or loaded state, with lancet **70c** ready to be biased to a puncturing position by a compressed drive spring **92c**. In this initial armed state, drive spring **92c** is in a compressed (i.e., loaded) state, ready to bias the lancet **70c** through a puncturing procedure upon release. In particular, lancet device **10c** is provided with drive spring **92c** compressed between proximal spring guide **86c** on carrier body **76c** and rear cap **24c**. The lancet **70c** is secured against forward movement into shield **14c** by a locking or actuation structure **110** extending between housing **12c** and lancet **70c**. Actuator **110** prevents release of lancet **70c** and, correspondingly, maintains compression of drive spring **92c** until a user of the lancet device **10c** is ready to carry out a puncturing procedure.

[00122] Actuator **110** generally comprises a sleeve portion **112** and one or more pivotal splints or tabs **114**, for example elastic splints, extending from the sleeve portion **112**. Sleeve portion **112** is disposed in an annular wall recess **116** defined in the inner surface of main body **20c** of housing **12c**. Main body **20c** is formed with a generally thicker annular wall in lancet device **10c** in comparison to lancet devices **10a**, **10b**. Sleeve portion **112** may be secured in wall recess **116** by a medical grade adhesive and/or preferably by being captured axially between wall recess **116** and annular rim **36c** on rear cap **24c** and thereby frictionally held in wall recess **116**. Actuator **110** is depicted with two generally inward-extending splints or tabs **114** engaging lancet **70c**. While this configuration is desirable, only one elastic splint **114** for engaging lancet **70c** is typically required, and additional splints **114** in excess of two may be also be provided.

[00123] The splints **114** extend generally rearward or in a proximal direction in main body **20c** and engage guide tabs **78c** on carrier body **76c** of lancet **70c**. Splints **114** are angled inward, in this instance, at approximately a 45° angle relative to Central Axis A to engage guide tabs **76c** in the initial state of lancet device **10c**. In particular, ends **118** of splints **114** engage guide tabs **78c** on carrier body **76c** to prevent lancet **70c** from releasing from the initial, armed state of lancet device **10c** and thereby maintain drive spring **92c** in a compressed state until lancet device **10c** is actuated by a user. Splints **114** are each connected by a hinge connection **120** to sleeve portion **112**. The hinge connection **120** may be a living hinge as illustrated as an exemplary embodiment of this structure. Ends **118** of splints **114**



engage a corner of guide tabs **78c**, such that distal movement of carrier body **76c** distally with respect to housing **12c** in absence of shield **14c** would cause splints **114** to generally compress between hinge connection **120** and the point of contact between guide tabs **78c**. As with lancet devices **10a**, **10b**, lancet device **10c** is actuated when a user depresses housing **12c** to retract (i.e., depress) shield **14c** therein. However, shield **14c** is now adapted to release actuator **110** between housing **12c** and lancet **70c**, thereby releasing compressed drive spring **92c** to bias the lancet **70c** through a puncturing procedure.

[00124] To facilitate actuation of lancet device **10c**, shield **14c** is adapted to engage and release actuator **110**. For this purpose, shield body **50c** may be formed with a tapered rear rim **122** at shield proximal end **54c**. The tapered rear rim **122** is generally tapered in the same direction as splints **114** to engage the distal or forward facing sides of splints **114**. The point of engagement for the tapered rear rim **122** is on splints **114** at a location between hinge connection **120** and the point of contact between guide tabs **78c**. The tapered rear rim **122** may define a taper of about 45° to correspond to the inward taper of splints **114**. In the initial, armed state of lancet device **10c**, the tapered rear rim **122** is in contact with splints **114** so that any rearward movement of shield **14c** into housing **12a** will immediately act upon the actuator **110** and splints **114** in particular. While the rear rim **122** is illustrated with a defined taper, it will be appreciated that such taper may be omitted and shield body **50c** formed as a cylindrical structure with a flat or blunted rear rim **122**.

[00125] With continued reference to FIGS. 13-18, use and operation of lancet device **10c** will now be discussed. As with previous embodiments, cover **100c** extending distally from carrier body **76c** is first removed by breaking the frangible connection with carrier body **76c** and withdrawing cover **100c** from forward opening **60c** in forward end wall **58c** of shield body **50c**. The forward end wall **58c** of shield body **50c** may then be placed in contact with the target location on the patient's body. As indicated, lancet device **10c** is initially provided in an armed state with lancet **70c** ready to initiate a puncturing procedure when compressed drive spring **92c** is released.

[00126] To carry out a puncturing procedure, the user grasps opposing sides of housing **12c** and exerts downwardly directed force in the direction of Arrow **X** on main body **20c** forcing shield body **50c** to retract into main body **20c**. This force causes an opposing force on forward end wall **58c** of shield body **50c**, causing shield body **50c** to retract axially within main body **20c**. As shield body **50c** retracts into main body **20c**, tapered rear rim **122** on rearward end **54c** of shield body **50c** and in engagement with splints **114** begins to move splints **114** radially outward toward sleeve portion **112**. Continued rearward movement of

shield body **50c** causes the splints **114** to continue their radial outward movement away from lancet **70c** until the splints **114** disengage from guide tabs **78c** and release the interference engagement therewith. The configuration of actuator **110** converts the axial movement of shield body **50c** into pivotal radial outward movement of splints **114** to effectuate actuation of lancet device **10c**.

[00127] With the potential energy in drive spring **92c** released, drive spring **92c** biases the lancet **70c** away from rear cap **24c** and through shield body **5cb**. During such propelling movement, corresponding guide tabs **78c** on carrier body **76c** and guide channels **80c** within shield body **50c** guide lancet **70c** axially through shield body **50c**. The biasing force imparted to lancet **70c** is preferably sufficient to cause the puncturing end **74c** of lancet **72c** to project a sufficient distance and with sufficient force from the forward opening **60c** of shield body **50c** to cause a puncture wound in the desired location on the patient's body. Moreover, during the propelling movement of lancet **70c**, proximal spring guide **86c** on carrier body **76c** releases from drive spring **92c** which remains connected to rear cap **24c**. Distal spring guide **88c** provides an abutment surface for engaging internal sleeve **96c** supporting retraction spring **94c** to prevent lancet **70c** from axial movement entirely out of shield body **50c** through forward opening **60c**.

[00128] As the lancet **70c** moves forward in the propelling movement, distal spring guide **88c** engages retraction spring **94c**. The biasing/propelling force provided by drive spring **92c** is at least in part applied to retraction spring **94c** by engagement of distal spring guide **88c** with retraction spring **94c**, which causes the retraction spring **94c** to compress toward distal end pocket **98c**. The retraction spring **94c** permits puncturing end **74c** of lancet **72c** to extend through forward opening **60c** in shield body **50c** a sufficient distance and with sufficient force to puncture the skin of the patient and initiate blood flow, and thereafter return lancet **70c** to a substantially fixed and stationary position within shield **14b**. In particular, as the retraction spring **94c** returns to a relaxed or unloaded state within shield body **50c**, the lancet **70c** is retracted in shield **14c** and returned to a generally stationary and fixed position within shield body **50c**. Thereafter, the engagement of retraction spring **94c** with distal spring guide **88c** maintains the lancet **70c** at a stationary and relatively fixed position within shield body **50c** and maintains puncturing end **74c** shielded within shield body **50c** preventing further movement of lancet **70c** to the puncturing position.

[00129] Referring to FIGS. 19-23, a fourth embodiment of a lancet device **10d** is generally illustrated, and generally comprises a housing **12d** and a lancet **70d** disposed in housing **12d**. Lancet device **10d** differs from lancet devices **10a-c** discussed previously, as lancet device

**10d** is not actuated through the retraction (i.e., depression) of a shield element into housing **12d**. However, lancet device **10d** is similar to lancet device **10c** discussed immediately above because lancet device **10d** is initially provided in an armed or loaded state, with lancet **70d** ready to be biased to the puncturing position by drive spring **92d** upon release of an interfering structure. In this initial, armed state, drive spring **92d** is in a compressed (i.e., loaded) state, ready to bias the lancet **70d** through a puncturing procedure upon repositioning lancet **70d** with respect to an interfering structure or engagement between housing **12d** and lancet **70d**. However, the configuration of the housing **12d**, lancet **70d**, and drive spring **92d** differ from previous embodiments and these differences will now be described.

[00130] Housing **12d** of lancet device **10d** comprises an elongated main body **20d** that generally defines a cylindrical and hollow configuration. The main body **20d** has a distal or forward end portion **22d**, and a rear cap **24d** forming a proximal or rearward end portion **26d** of the main body **20d**. The interior of housing **12d** is generally open and comprises an internal cavity **28d**. The internal cavity **28d** is closed at the rearward end due to rear cap **24d**, and includes a front opening **30d** defined in forward end portion **22d** of main body **20d**, and through which lancet **70d** at least partially extends when lancet device **10d** is actuated. Main body **20d** and rear cap **24d** may be integrally formed. Typically, main body **20d** and rear cap **24d** are separate elements that are affixed together to form housing **12d**, as illustrated, which facilitates assembly of lancet device **10d**. As examples, main body **20d** and rear cap **24d** may be affixed together through an appropriate medical grade adhesive, and/or may be connected using inter-engaging structures providing a mechanical engagement therebetween, such as a friction-fit or a snap-fit construction. For example, main body **20d** may include an annular rim **32d** defining an annular groove **34d**, and the rear cap **24a** may include a mating annular rim **36d** having a mating annular lip **38d** as mating elements in much the same manner as described previously.

[00131] In contrast to previous embodiments, distal or forward end portion **22d** of main body **20d** comprises an axially rearward-extending internal sleeve **98d** that defines a distal end pocket **98d** for receiving and supporting retraction spring **94d**. In previous embodiments, the retraction spring(s) were disposed in a distal end pocket formed as part of the forward end wall of the actuating shield structure. This structure is now provided at the forward end portion **22d** of main body **20d** of housing **12d**. Additionally, main body **20d** of housing **12d** further comprises an actuation structure or actuator **130** for causing actuation of lancet **70d** and corresponding release of drive spring **92d**. Actuator **130** generally comprises an actuating button or lever **132** that is typically pivotally associated with main body **20d**. The

pivotal association with main body **20d** may be in the form of a living hinge or equivalent structure and lever **132** may thus be integrally formed with main body **20d**. A tab member **134** depends from an inner side of actuating lever **132** for engaging lancet **70d** and causing actuation of the same. In particular, lever **132** is pivotally connected to main body **20d** so that the lever **132** may be depressed inward into internal cavity **28d** in main body **20d**, such that tab member **134** interacts with lancet **70d** to cause actuation or release of lancet **70d**.

[00132] Main body **20d** of housing **12d** includes opposing inner sidewalls **136** each defining an internal guide channel **138** for guiding movement of lancet **70d** within main body **20d**. Guide channels **138** may be formed as grooves or recesses in the inner sidewalls **136**, or be formed in a structure extending inward from the respective sidewalls **136**. Guide channels **138** are generally L-shaped and comprise a longitudinally extending main channel **140** and a generally transversely extending side channel **142**. Main channel **140** extends distally forward from an area proximate to tab member **134** to a location proximate to retraction spring **94d**. Main channel **140** defines an abutment surface or stop **144** in guide channels **138** to provide a stop for carrier body **76d** of lancet **70d** to prevent axial movement of the lancet **70d** entirely out of main body **20d** through front opening **30d**.

[00133] Side channel **142** is contiguous with main channel **140** and extends approximately oblique to transverse to main channel **140**. Side channel **142** extends upward in a direction towards lever **132**. While side channel **142** is formed generally oblique to main channel **140**, side channel **142** and main channel **140** define a tapered corner or vertex **146** at their intersection. The corner **146** defines an angle of less than about 90°. The opposing side channels **142** in main body **20d** are used to initially receive guide tabs **78d** on carrier body **76d** for maintaining carrier body **76d** in a dynamically stable and balanced position, thereby opposing the force acting on guide tabs **78d** by drive spring **92d**, and restraining compressed drive spring **92d**. Corner **146** is used to define the transition between main channel **140** and side channel **142**. Movement of guide tabs **78d** towards side channels **142** allows carrier body **76d** to transition from a position of dynamic stability to a position of dynamic instability. Accordingly, side channels **142** initially maintain the positioning of guide tabs **78d**, with guide tabs **78d** in interference engagement with corners or vertexes **146** to maintain the positioning of guide tabs **78d** until lancet device **10d** is to be actuated.

[00134] Lancet **70d** is formed in a generally analogous manner as previous embodiments and comprises a lancet **72d** with a puncturing end **74d** at the forward end thereof, and a carrier body **76d** supporting lancet **72d** at the rearward end thereof. The carrier body **76d** comprises a pair of guide tabs **78d** on an external surface thereof that engage guide channels

**138.** Lancet **70d** is adapted for axial movement through the internal cavity **28d** of main body **20d** between an initial position wherein guide tabs **78d** are disposed in side channels **142** and the puncturing end **74a** is disposed entirely within main body **20d**, to a puncturing position wherein the puncturing end **74d** extends beyond the front opening **30d** in main body **20d** a sufficient distance to cause a puncture wound on a patient's body while guide tabs **78d** remain disposed in main channels **140**. Further details regarding the operation of lancet device **10d** and the movement of lancet **70d** are provided hereinafter.

[**00135**] Carrier body **76d** further comprises a proximal or rear rim **148** at the rearward end thereof. Rim **148** defines the forward end of proximal spring guide **86d** and typically has a diameter larger than the diameter of distal spring guide **88d** of carrier body **76d**. Rim **148** is provided as a contact structure or surface on lancet **70d** for engagement by tab member **134** to cause actuation of lancet device **10d**. The diameter of rim **148** is also typically sized to be at least equal to the diameter of drive spring **92d** and provides a contact structure or surface that restrains compressed drive spring **92d** in the initial state of lancet **70d**. During actuation of lancet device **10d**, drive spring **92d** acts against rear rim **148** to bias lancet **70d** to the puncturing position, as described herein. Moreover, carrier body **76d** additionally comprises two opposing posts **150** cooperating with guide channels **138**, and main channels **140** in particular. Posts **150** engaged in guide channels **138** permit at least a limited amount of pivotal movement by carrier body **76d** about an axis passing through posts **150**, and maintain lancet **70d** associated with guide channels **138** until guide tabs **78d** align with main channels **140** during the actuation sequence of lancet device **10d**.

[**00136**] In the initial state of lancet device **10d**, drive spring **92d** is at least partially compressed between rear rim **148** on carrier body **76d** and rear cap **24d**, and typically has sufficient stored potential energy to conduct a skin-puncturing procedure. The rearward or proximal end of drive spring **92d** is typically secured to rear cap **24d** in the manner discussed previously in this disclosure. The forward or distal end of drive spring **92d** is associated with carrier body **76d** and may be secured to rear rim **148** by similar means discussed previously, as by suitable adhesive or direct mechanical attachment. Drive spring **92d** generally defines an off-axis or off-center spring arrangement, wherein drive spring **92d** extends at upward angle toward lever **132**. Drive spring **92d** is stabilized in the off-center and compressed (i.e., loaded) arrangement by engagement of guide tabs **78d** in side channels **142** of guide channels **138**. Corners **146** define an interfering engagement and point of transition for guide tabs **78d** to maintain drive spring **92d** in a compressed (i.e., loaded) state and in the off-center configuration. The acute angle defined by corner **146** defines a receiving notch **152** for guide

tabs **78d** to prevent guide tabs **78d** from readily releasing from side channels **142** until intended actuation by a user. Thus, engagement of guide tabs **78d** in guide channels **138** forms an interfering structure to secure lancet **70d** against forward movement in main body **20d** and, correspondingly, maintains compression of drive spring **92d** until a user of the lancet device **10d** is ready to carry out a puncturing operation.

[00137] With continued reference to FIGS. 19-23, use and operation of lancet device **10d** will now be discussed. As with previous embodiments, a cover (not shown) extending distally from carrier body **76d** may be provided with carrier body **76d**. As with previous embodiments, such a cover is removed by breaking the frangible connection with carrier body **76d** and withdrawing the cover from front opening **30d** in main body **20d**. The forward end rim **42d** of main body **20d** may then be placed in contact with the target location on a patient's body. As indicated previously, lancet device **10d** is initially provided in an armed state with lancet **70d** ready initiate a puncturing procedure when compressed drive spring **92d** is released.

[00138] To carry out a puncturing procedure, the user grasps opposing sides of housing **12d** and exerts downwardly directed force on lever **132** pivotally connected to main body **20d**, causing lever **132** to depress into internal cavity **28d** of main body **20d**. As lever **132** is depressed into main body **20d**, tab member **134** interacts with rear rim **148** on carrier body **76d**. In particular, the downward force applied to lever **132** causes tab member **134** to move rear rim **148** downward in the internal cavity **28d**. As rear rim **148** of carrier body **76d** moves downward in internal cavity **28d** of main body **20d**, the carrier body **76d** will substantially simultaneously pivot about posts **150** in main channel **140** of guide channels **138**. Also substantially simultaneously, guide tabs **78d** received in side channels **142** slide downward in side channels **142** until passing corners **146** which has the effect of moving carrier body **76d** from a first state of being dynamically balanced to a second state of being dynamically unbalanced, thereby allowing drive spring **92d** to propel carrier body **76d** through main body **20d** until the puncturing end **74d** of lancet **72d** projects through front opening **30d** in main body **20d**. The downward movement of guide tabs **78d** in side channels **142** has the optional effect of further compressing drive spring **92d**.

[00139] As the lever **132** is continued to be depressed into main body **20d**, guide tabs **78d** eventually clear corners **146** and disengage from side channels **142**. At this point, guide tabs **78d** align with main channel **140** of guide channels **138** and are free to move forward therein under the biasing force of drive spring **92d**. Correspondingly, with the engagement between guide tabs **78d** and corners **146** released, the drive spring **92d** is free to bias lancet **70d** to the

puncturing position. With the stored potential energy in drive spring **92d** released, drive spring **92d** thereafter biases the lancet **70d** away from rear cap **24d** and through main body **20d**. During such propelling movement, the engagement of guide tabs **78d** in guide channels **138** guides lancet **70d** axially through main body **20d**. The distal biasing energy imparted to lancet **70d** is preferably sufficient to cause the puncturing end **74d** of lancet **72d** to project a sufficient distance and with sufficient force from the front opening **30d** in main body **20d** to cause a puncture wound in the desired location on the patient's body. Moreover, during the propelling movement of lancet **70d**, proximal spring guide **86d** on carrier body **76d** releases from drive spring **92d** which remains connected to rear cap **24d**. The engagement of posts **150** with stops **144** in guide channels **138** prevents lancet **70d** from axial movement entirely out of main body **20d** through front opening **30d**.

[00140] As the lancet **70d** moves forward in the propelling movement, distal spring guide **88d** engages retraction spring **94d**. The biasing force of drive spring **92d** is at least in part applied to retraction spring **94d** by engagement of distal spring guide **88d** with retraction spring **94d**, which causes the retraction spring **94d** to compress toward distal end pocket **98d**. The retraction spring **94d** permits puncturing end **74d** of lancet **72d** to extend through front opening **30d** in main body **20d** a sufficient distance and with sufficient force to puncture the skin of the patient and initiate blood flow, and thereafter return lancet **70d** to a generally fixed and stationary position within housing **12d**. In particular, as the retraction spring **94d** returns to a relaxed or unloaded state within main body **20d**, the lancet **70d** is retracted in main body **20d** and returned to a generally fixed and stationary position within main body **20d**. Thereafter, the engagement of retraction spring **94d** with distal spring guide **88d** maintains the positioning of lancet **70d** within main body **20d** with puncturing end **74d** of lancet **72d** shielded within housing **12d**, and prevents further movement of lancet **70d** to the puncturing position.

[00141] Referring to FIGS. 24-30, a fifth embodiment of a lancet device **10e** is generally illustrated, and comprises the same basic components or elements as lancet devices **10a-c** described previously. Generally, lancet device **10e** comprises a housing **12e**, a shield **14e** movably associated with the housing **12e**, and a lancet **70e** movably disposed in housing **12e**. As the basic components of lancet device **10e** are substantially similar to the corresponding components of lancet devices **10a-c** discussed previously, only distinct differences between these general components will be discussed herein, along with the use and sequence of operation of lancet device **10e**.

[00142] The sequence of operation of lancet device **10e** generally follows the sequence of operation of lancet devices **10a-c**, wherein lancet device **10e** is armed and actuated through the retraction (i.e., depression) of shield **14e** into housing **12e**. Generally, in lancet device **10e**, arming and actuation of lancet device **10e** occurs as a result of proximal or rearward end **54e** of shield body **50e** of shield **14e** engaging a structure within housing **12e** that causes compression (i.e., loading) of drive spring **92e** and, upon release of such compression, drive spring **92e** biases lancet **70e** through a propelling movement resulting in puncturing end **74e** of lancet **72e** projecting from shield **14e** for puncturing procedure the skin of a patient, as discussed in more detail herein.

[00143] In lancet device **10e**, shield **14e** comprises a shield body **50e** with a rear ledge or rim **162** at shield proximal end **54e**. The rear ledge or rim **162** is generally adapted for contact or engagement with a slide plate **164** disposed in housing **12e** to cause actuation of lancet device **10e** as described in detail herein. Slide plate **164** forms the structure for compressing drive spring **92e** alluded to previously. Rear ledge or rim **162** is also adapted to engage forward rim **42e** of main body **20e** of housing **12e** to prevent shield body **50e** from axially sliding completely out of housing **12e** through front opening **30e** defined in the forward end wall **58e** of shield body **50e**. Rear rim **162** is sized such that it may slide along the inner surface of main body **20b** when shield body **50e** is retracted (i.e., depressed) into main body **20e**, as will occur when the lancet device **10b** is actuated by a user.

[00144] Slide plate **164** forms the internal structure in main body **20e** of housing **12e** which is used to cause compression of drive spring **92e** thereby storing potential energy in drive spring **92e** which, upon release, is used to bias lancet **70e** to the puncturing position. Slide plate **164** is disposed in main body **20e** of housing **12e** to be in contact with rear rim **162** of shield body **50e**. Slide plate **164** is associated with rear rim **162** of shield body **50e** so that slide plate **164** may move rearward with shield body **50e** as shield body **50e** is retracted (i.e., depressed) into main body **20e** of housing **12e** to arm and actuate lancet device **10e**. Slide plate **164** defines a generally centrally-located keyhole or key opening **166** that is sized and shaped to generally conform to the transverse cross-sectional shape of carrier body **76e** of lancet **70e**, to allow the cross-section of carrier body **76e** to pass therethrough during actuation of lancet device **10e**. In particular, keyhole **166** comprises a central, typically circular-shaped portion **168** and two contiguous laterally-extending notches **170**, which define a shape that permits the transverse cross-section of carrier body **76e** to pass therethrough during actuation of lancet device **10e**, as discussed further herein.



[00145] A further difference in lancet device **10e** when compared to lancet devices **10a-c** discussed previously lies in the formation of rear cap **24e**, and the interaction therewith by slide plate **164** and shield body **50e** to cause arming and actuation of lancet device **10e**. As in previous embodiments, rear cap **24e** comprises an annular rim **36e** that engages an annular rear rim **32e** of main body **20e** of housing **12e**. In particular, annular lip **38e** on annular rim **36e** engages annular groove **34e** defined in annular rim **32e** to join rear cap **24e** to main body **20e**. However, in lancet device **10e**, annular rim **36e** is elongated and extends distally a greater distance into main body **20e** of housing **12e**, so as to be positioned proximate to the rear rim **162** of shield body **50e** in the initial state of lancet device **10e**. Annular rim **36e** defines a tapered internal cam surface **172**, which is shaped to impart a specific cam motion to slide plate **164** due to contact therewith and ultimately cause arming and actuation of lancet device **10e** as described hereinafter.

[00146] In the initial state of lancet device **10e**, drive spring **92e** is associated with lancet **70e**, with the drive spring **92e** extending from the inner side of rear cap **24e** to carrier body **76e**. In lancet device **10e**, carrier body **76e** is further formed with a proximal or rear rim **174** at the rearward end thereof. Rim **174** generally defines the forward end of proximal spring guide **86e** and typically has a diameter larger than the diameter of distal spring guide **88e** and typically at least equal to the diameter of the forward end of drive spring **92e**. Rim **174** defines a contact structure or surface on carrier body **76e** that is used to compress drive spring **92e** to place the lancet device **10e** into a loaded or armed state. Once the drive spring **92e** is released, thereby releasing the potential energy stored therein during the compression of drive spring **92e**, the drive spring **92e** will act against rear rim **174** to bias lancet **70e** to the puncturing position. Guide tabs **78e** are typically formed integrally with rear rim **174** and extend laterally therefrom.

[00147] With the various distinguishing components of lancet device **10e** now set forth, use and operation of lancet device **10e** will now be described with continued reference to FIGS. 24-30. Prior to use, cover **100e** extending distally from carrier body **76e** is removed by breaking the frangible connection with carrier body **76e**, and withdrawing cover **100e** from forward opening **60e** in forward end wall **58e** of shield body **50e** in the manner described previously. The forward end wall **58e** of shield body **50e** may then be placed in contact with a target location on a patient's body. In the initial, unarmed state of lancet device **10e**, the drive spring **92e** is substantially uncompressed (i.e., unloaded) and extends from rear rim **174** on carrier body **76e** to rear cap **24e**. In the initial, unarmed state of lancet device **10e**, drive spring **92e** is in a relaxed condition and acts on rear rim **174** on carrier body **76e** to position

lancet **70e** at a generally fixed and stationary position within main body **20e** of housing **12e**, wherein the lancet **70e** occupies a substantially fixed position relative to main body **20e** and shield body **50e**. Additionally, the drive spring **92e** acting on rear rim **174** causes the carrier body **76e** to engage (i.e., contact) the rear side of slide plate **164**. In particular, drive spring **92e** in its relaxed or unloaded initial state, causes the front side or surface of rear rim **174** and front surface **82e** of guide tabs **78e** to be in substantial contact with the rear side or surface of slide plate **164**. Moreover, in the initial state of lancet device **10e**, slide plate **164** is positioned in contact with the rear rim **162** of shield body **50e** so that rear rim **174** and guide tabs **78e** of carrier body **76e** are offset vertically from the keyhole **166** defined in slide plate **164**. Accordingly, in the initial state of lancet device **10e**, rear rim **174** and guide tabs **78e** are in interference engagement with the rear side of slide plate **164**.

[00148] To use the lancet device **10e**, the user grasps opposing sides of housing **12e** and exerts downwardly directed force on main body **20e** thereof in the direction of Arrow **X**. This force causes an opposing force on forward end wall **58e** of shield body **50e**, causing shield body **50e** to retract (i.e., depress) axially within main body **20e**. As shield body **50e** retracts into main body **20e**, rearward end **54e** of shield body **50e** moves proximally (i.e., rearward) toward rear cap **24e**. In particular, rear rim **162** at the rearward end **54e** of shield body **50e** moves rearward while simultaneously interacting with cam surface **172**. Further, as rear rim **162** of shield body **50e** moves rearwardly in main body **20e**, slide plate **164** also begins to move rearwardly in combination with the rear rim **162** toward rear cap **24e**, due to the engagement between slide plate **164** and rear rim **162**. Additionally, lancet **70e** will move rearward with shield body **50e** and slide plate **164** due to the offset interference engagement between rear rim **174** and guide tabs **78e** and slide plate **164**. The rearward movement of lancet **70e** will further begin to compress drive spring **92e**, due to the engagement of drive spring **92e** with the rear side of rear rim **174** on carrier body **76e**.

[00149] The downward movement imparted to housing **12e** also causes the slide plate **164** to interact with tapered cam surface **172** defined by annular rim **36e** of rear cap **24e**. Due to the tapered shape of cam surface **172** from the forward or distal end of annular rim **36e** toward the Central Axis **A** of lancet device **10e**, slide plate **164** moves downward in internal cavity **28e** of main body **20e** as the slide plate **164** is retracted in main body **20e**. Accordingly, as shield body **50e** is retracted (i.e., depressed) into main body **20e** of housing **12e**, slide plate **164** moves rearwardly and downward in main body **20e**, and this combined movement occurs substantially simultaneously. Additionally, continued rearward movement

of shield body **50e** has the effect of compressing the drive spring **92e** and storing the potential energy necessary to bias the lancet **70e** to the puncturing position.

[00150] Once the slide plate **164** moves downward to a position where the transverse cross-sectional shape of the carrier body **76e** defined at the location of rear rim **174** and guide tabs **78e** on carrier body **76e** matches the corresponding profile of keyhole **166**, the interfering engagement restraining the drive spring **92e** is removed and the potential energy stored in drive spring **92e** is released. With the stored potential in drive spring **92e** released and providing a biasing force acting on lancet **70e**, the drive spring **92e** biases the lancet **70e** away from rear cap **24b** and through shield body **50e**. During such propelling movement, the corresponding guide tabs **78e** and guide channels **80b** guide lancet **70b** axially through shield body **50e**. The biasing force acting on lancet **70e** is preferably sufficient to cause the puncturing end **74e** of lancet **72e** to project a sufficient distance and with sufficient force from the forward opening **60e** in shield body **50e** to cause a puncture wound at the target location on the patient's body. Moreover, during the propelling movement of lancet **70e**, proximal spring guide **86e** on carrier body **76e** releases from drive spring **92e** which remains connected to rear cap **24e**.

[00151] As the lancet **70e** moves forward in the propelling movement, distal spring guide **88e** engages retraction spring **94e**. The biasing/propelling force provided by drive spring **92e** is at least in part applied to retraction spring **94e** by engagement of distal spring guide **88e** with retraction spring **94e**, which causes the retraction spring **94e** to compress toward distal end pocket **98e**. The retraction spring **94e** permits puncturing end **74e** of lancet **72e** to extend through forward opening **60e** in shield body **50e** a sufficient distance and with sufficient force to puncture the skin of the patient and initiate blood flow, and thereafter returns lancet **70e** to a substantially fixed and stationary position within shield **14e**. Distal spring guide **88e** provides an abutment surface for engaging internal sleeve **96e** in shield body **50e** supporting retraction spring **94e** to prevent lancet **70e** from axial movement entirely out of shield body **50e** through forward opening **60e**. As the retraction spring **94e** returns to a relaxed or unloaded state within shield body **50e**, the lancet **70e** is retracted in shield **14e** and returned to a substantially fixed and stationary positioned within shield body **14e**. Thereafter, the engagement of retraction spring **94e** with distal spring guide **88e** maintains the lancet **70e** at a generally fixed position within shield body **50e**. This engagement further maintains puncturing end **74e** shielded within shield body **50e**, and prevents further movement of lancet **70e** to the puncturing position.

[00152] Referring to FIGS. 31-37, a sixth embodiment of a lancet device **10f** is generally illustrated, and generally comprises a housing **12f** and a lancet **70f** disposed in housing **12f**. Lancet device **10f** is similar in structure to lancet device **10d** discussed previously but includes a plate for actuating the device in a similar manner to lancet device **10e** discussed immediately above. As with lancet device **10d**, lancet device **10f** is not actuated through the retraction (i.e., depression) of a shield element into housing **12f**, and is initially provided in an armed or loaded state, with lancet **70f** ready to be biased to the puncturing position by drive spring **92f** upon release of an interfering structure. The interfering structure in lancet device **10f** is a plate similar that described previously and additional details of which specific to the present embodiment will be provided herein.

[00153] In the initial, armed state of lancet device **10f**, drive spring **92f** is in a compressed (i.e., loaded) state, ready to bias the lancet **70f** through a puncturing procedure upon release. As the configuration of the housing **12f**, lancet **70f**, and drive spring **92f** are generally similar to lancet device **10d** discussed previously, the following discussion will build upon the previously discussed structure of lancet device **10d**.

[00154] Housing **12f** of lancet device **10f** comprises an elongated main body **20f** that generally defines a cylindrical and hollow configuration. The main body **20f** has a distal or forward end portion **22f**, and a rear cap **24f** forming a proximal or rearward end portion **26f** of the main body **20f**. The interior of housing **12f** is generally open and comprises an internal cavity **28f**. The internal cavity **28f** is closed at the rearward end due to rear cap **24f**, and includes a front opening **30f** defined in forward end portion **22f** of main body **20f**, and through which lancet **70f** extends when lancet device **10f** is actuated. Main body **20f** and rear cap **24f** may be integrally formed. Typically, main body **20f** and rear cap **24f** are separate elements that are affixed together to form housing **12f**, in the manner described previously, but may also be integral also in the manner described.

[00155] In lancet device **10f**, distal or forward end portion **22f** of main body **20d** comprises an axially rearward-extending internal sleeve **96f** which defines a distal end pocket **98f** for receiving and supporting retraction spring **94f**. Forward rim **42f** at the forward end portion **22f** of main body **20f** is adapted to be placed in contact with a patient's body during use of lancet device **10f**. Additionally, main body **20f** comprises an actuation structure or actuator **180** for causing actuation of lancet **70f** and corresponding release of compressed drive spring **92f**. Actuator **180** generally comprises an actuating button or lever **182** that is pivotally associated with main body **20f**. The pivotal association with main body **20f** may be in the form of a living hinge **183** or equivalent structure and lever **182** may thus be integrally

formed with main body **20f**. Actuator **180** further comprises a plate member **184**, which depends from an inner side of actuating lever **182** and extends downward into internal cavity **28f** of main body **20f** of housing **12f**. Plate member **184** is oriented substantially transverse to the Central Axis A of main body **20f** in the initial state of actuating lever **182**. Plate member **184** may be formed integrally with lever **182** or be provided as a separate component from lever **182** and be joined thereto. For example, lever **182** may define a recess **186** that accepts a tab **188** extending from plate member **184** to connect plate member **184** to lever **182**. Tab **188** may be secured in recess **186** via friction fit and/or with an adhesive. The pivotal connection between lever **182** and main body **20f** is provided so that plate member **184** may interact with lancet **70f** and, further, drive spring **92f** to release the compressed drive spring **92f** and cause actuation of lancet device **10f**.

[00156] Main body **20f** of housing **12f** comprises opposing inner sidewalls **190** each defining an internal guide channel **192** for guiding movement of lancet **70f** within main body **20f**. Guide channels **192** may be formed as longitudinally extending grooves or recesses in the inner sidewalls **190**, or may be formed as part of a raised structure extending inward from sidewalls **190**. The guide channels **192** are adapted to receive to receive guide tabs **78f** on carrier body **76f** to guide movement of lancet **70f** within main body **20f**. Guide channels **190** each define an end surface or stop **194**, which may be used to provide a stop for guide tabs **78f** to prevent lancet **70f** from axial movement entirely out of main body **20f** through front opening **30f** after the lancet device **10f** is actuated. However, desirably distal spring guide **88f** may be formed to provide an abutment surface for engaging internal sleeve **96f** in shield body **50f** supporting retraction spring **94f** to prevent lancet **70f** from axial movement entirely out of shield body **50f** through forward opening **60f**.

[00157] Lancet **70f** is formed in a generally analogous manner to lancet **70d** of lancet device **10d** discussed previously, with carrier body **76f** including two outward extending guide tabs **76f** and supporting a lancet **72f** with a puncturing end **74f** at the forward end thereof. As in previous embodiments, guide tabs **78f** extending laterally outward from carrier body **76f** engage guide channels **190** in main body **20f**. Carrier body **76f** further comprises a proximal or rear rim **196** at the rearward end thereof. Rim **196** generally defines the forward end of proximal spring guide **86f** and typically has a diameter larger than the diameter of distal spring guide **88f** on carrier body **76f**, and typically at least equal to the diameter of the forward end of drive spring **92f**. Rim **196** is provided as a contact structure or surface on lancet **70f** for interference engagement with plate member **184** to prevent actuation of lancet device **10f**, and maintain compression of drive spring **92f** in the initial, pre-actuated state of

lancet device **10f**. As indicated, the diameter of rim **196** is also typically sized to be at least equal to the diameter of drive spring **92f** and provides a contact structure or surface that maintains drive spring **92f** in a compressed state in the initial, pre-actuated state of lancet device **10f**. During actuation of lancet device **10f**, drive spring **92f** will act against rim **196** to bias lancet **70f** to the puncturing position, as described further herein. In general, lancet **70f** is adapted for axial movement through the internal cavity **28f** of main body **20f** between an initial position wherein plate member **184** is in interference engagement with the lancet **70f**, thereby holding or maintaining drive spring **92f** in a compressed or loaded state, to a puncturing position where the puncturing end **74f** of lancet **72f** extends beyond the front opening **30f** in main body **20f** a sufficient amount to cause a puncture wound on a patient's body.

[00158] Plate member **184** defines a generally centrally-located keyhole or key opening **197** that is sized and shaped to match the transverse cross-sectional shape or outline of carrier body **76f** of lancet **70f** to allow the carrier body **76f** to pass therethrough during actuation of lancet device **10f**. In particular, keyhole **197** comprises a central, typically circular-shaped portion **198** and two contiguous laterally extending notches **200** which define a shape that permits the carrier body **76f** to pass therethrough during actuation of lancet device **10f**.

[00159] With the general components of lancet device **10f** now set forth, use and operation of lancet device **10f** will now be described with continued reference to FIGS. 31-37. Prior to use, cover **100f** extending distally from carrier body **76f** is removed by breaking the frangible connection with carrier body **76f**, and withdrawing cover **100f** from the front opening **30f** in main body **20f** in the manner described previously. In the initial, pre-actuated state of lancet device **10f**, plate member **184** is positioned relative to carrier body **76f** such that the rear rim **196** and guide tabs **78f** on carrier body **76f** are offset from keyhole **197** and, therefore, in interference engagement with the rear side of plate member **184**. In particular, the transverse cross-sectional shape defined by the carrier body **76f** at the location of rear rim **196** and guide tabs **78f** is offset, typically vertically offset, from keyhole **197**. As a result, drive spring **92f** is held in a compressed, loaded state between rear rim **196** on carrier body **76f** and rear cap **24f**. The rearward or proximal end of drive spring **92f** may be secured to rear cap **24f** in the manner discussed previously in this disclosure. The forward or distal end of drive spring **92f** may be associated with the proximal spring guide **86f** and rear rim **196** of carrier body **76f** in the manner described previously, and may be secured to rear rim **196** by suitable means such as by adhesive and/or direct mechanical attachment.

[00160] To carry out a puncturing procedure, the user grasps opposing sides of housing 12f and places the forward rim 42f of main body 20f in contact with a target location on a patient's body. The user then exerts downward pressure in the direction of Arrow X on lever 182, causing lever 182 to pivot (i.e., depress) into internal cavity 28f of main body 20f. As lever 182 pivots downward in internal cavity 28f, plate member 184 also moves downward in internal cavity 28f while initially maintaining an interference engagement with lancet 70f and thereby continuing to maintain the drive spring 92f in a compressed state. In particular, plate member 184 initially maintains an interference engagement with lancet 70f, wherein the forward side or surface of rear rim 196 and forward side or surface of guide tabs 78f on carrier body 76f are in interference engagement with the rearward side or surface of plate member 184 thereby maintaining the drive spring 92f compressed between rear rim 196 and rear cap 24a. As the lever 182 is continued to be depressed into main body 20a, keyhole 197 in plate member 184 eventually aligns with a matching transverse cross-sectional shape defined by carrier body 76f at the location of the rear rim 196 and guide tabs 78f, thereby permitting the carrier body 76f to pass through keyhole 197. As the interference engagement between the rear rim 196 and guide tabs 78f and plate member 184 is released, the stored potential energy in drive spring 92e is also released and used to move the lancet 70f to the puncturing position.

[00161] As shown in FIGS. 35-37, the pivotal movement of lever 182 results in a corresponding pivotal movement by plate member 184. As a result, as plate member 184 is pivoted downward into main body 20f, the plate member 184 begins to define an angle  $\alpha$  with an axis perpendicular PA to the Central Axis A of lancet device 10f and housing 12f in particular. As the lever 182 is further depressed into main body 20f, the angle formed by plate member increases to angle  $\alpha'$ . The angular orientation of plate member 184 causes keyhole 197 to be at a slight angular orientation relative to Central Axis A. As a result, as plate member 184 moves downward and slightly forward in main body 20f, keyhole 197 does not align exactly along Axis PA but at an angle to this axis. Due to the angular "offset" between keyhole 197 and the Central Axis A of main body 20f, the matching transverse cross-sectional shape defined by carrier body 76f at the location of the rear rim 196 and guide tabs 78f will not pass easily through keyhole 197 unless the size of keyhole 197 is increased to compensate for the angular orientation of plate member 184. Therefore, in lancet device 10f it is desirable to increase the size of keyhole 197 to compensate for the forward angular movement of plate member 184. Alternatively, plate member 184 could be positioned in a track such that pivotal movement of lever 182 translates into linearly tracked movement of

plate member 184. Plate member 184 would still allow for providing clearance for rear rim 196 and guide tabs 78f to pass through keyhole 197.

[00162] With the stored potential in drive spring 92f released and providing a biasing force acting on lancet 70f, the drive spring 92f biases the lancet 70f away from rear cap 24f and through main body 20f. During such propelling movement, the engagement of guide tabs 78f in guide channels 192 guides lancet 70f axially through main body 20f. The biasing force applied to lancet 70f is preferably sufficient to cause the puncturing end 74f of lancet 72f to project a sufficient distance and with sufficient force from the front opening 30f in main body 20f to cause a puncture wound in the desired location on the patient's body. Moreover, during the propelling movement of lancet 70f, proximal spring guide 86f on carrier body 76f releases from drive spring 92f which remains connected to rear cap 24f. As the lancet 70f moves forward in the propelling movement, distal spring guide 88f engages retraction spring 94f. The biasing/propelling force of drive spring 92f is at least in part applied to retraction spring 94f by engagement of distal spring guide 88f with retraction spring 94f, which causes the retraction spring 94f to compress toward distal end pocket 98f. The retraction spring 94f is adapted to permit puncturing end 74f of lancet 72f to extend through front opening 30f in main body 20f a sufficient distance and with sufficient force to puncture the skin of the patient and initiate blood flow, and thereafter return lancet 70f to a substantially fixed and stationary position within housing 12f. As indicated, distal spring guide 88f desirably provides an abutment surface for engaging internal sleeve 96f supporting retraction spring 94f to prevent lancet 70f from axial movement entirely out of main body 20f of housing 12f through front opening 30f. As the retraction spring 94f returns to a relaxed or unloaded state within main body 20f, the lancet 70f is retracted in main body 20f and returned to a substantially fixed and stationary positioned within main body 20f. Thereafter, the engagement of retraction spring 94f with distal spring guide 88f maintains the lancet 70f within main body 20f, with the puncturing end 74f of lancet 72f shielded within housing 12f and preventing further movement of lancet 70f to the puncturing position.

[00163] Referring to FIGS. 38-43, a seventh embodiment of a lancet device 10g is shown and which is a variation of lancet device 10f described immediately previously. Lancet device 10g is similar in all respects to lancet device 10f described immediately above, except for comprising a different configuration of actuation structure or actuator 180g, which will now be detailed. Actuator 180g of lancet device 10g replaces the pivoting lever 182 of actuator 180 of lancet device 10f with a depressible button 182g, which allows plate member 184g to be depressed into main body 20g directly along Axis PA, such that plate member



**184g** no longer pivots into main body **20g** and thereby form an angle with Axis **PA**, as was the case with the lever **182** and depending plate member **184** of actuator **180** in lancet device **10f**. Other than the foregoing difference between actuator **180g** of lancet device **10g** and actuator **180** of lancet device **10f**, all other aspects of lancet device **10g** are identical to lancet device **10f** described previously.

[00164] As further shown in the FIGS. 31-43 associated with lancet devices **10f**, **10g**, actuation structures or actuators **180**, **180g** of these devices comprise a structure for engaging main bodies **20f**, **20g** of housing **12f**, **12g** such that, once actuation structures or actuators **180**, **180g** are depressed, the actuators **180**, **180g** are prevented from returning to their initial positions. In actuators **180**, **180g**, one or more detents **202**, **202g** are provided on a proximal or rearward end of lever **182** and a proximal or rearward end of button **182g**, respectively. Detents **202**, **202g** are adapted to engage in a snap-fit or friction-fit manner with a mating recess **204** defined in main bodies **20f**, **20g**. Recesses **204**, **204g** in main bodies **20f**, **20g** are provided opposite to the proximal or rearward end of lever **182** and the proximal or rearward side of button **182g**, respectively. In operation, as lever **182** and button **182g** are depressed into main bodies **20f**, **20g**, respectively, detents **202**, **202g** successively engage the mating recesses **204**, **204g** in main bodies **20f**, **20g**. The mating engagement of detents **202**, **202g** in mating recesses **204**, **204g** prevents lever **182** and button **182g** from returning to their initial positions. The use of multiple detents **202**, **202g** allows lever **182** and button **182g** to be moved in discrete downward steps or stages to the actuating position, where keyholes **196**, **196g** defined in plate members **184**, **184g** align with the matching or corresponding transverse cross-sectional shape of carrier bodies **76f**, **76g** to permit lancets **70f**, **70g** to move to the puncturing position.

[00165] Referring to FIGS. 44-52, an eighth embodiment of a lancet device **10h** is generally illustrated, and generally comprises a housing **12h** and a lancet **70h** disposed in housing **12h**. Lancet device **10h** differs from lancet devices **10a-c**, **e** discussed previously, as lancet device **10h** is not actuated through the retraction (i.e., depression) of a shield element into housing **12h**. However, lancet device **10h** is similar to lancet devices **10d**, **10f**, and **10g** discussed previously because lancet device **10h** is initially provided in an armed or loaded state, with lancet **70h** ready to be biased to the puncturing position by drive spring **92h** upon release or removal of an interfering engagement or structure, and likewise comprises a depressible actuation structure or actuator for releasing or removing the interference engagement. Additionally, lancet device **10h** incorporates a cutting and shearing concept such as that utilized in lancet devices **10a**, **10b** to remove the interference engagement. As in

previous embodiments, in the initial armed state of lancet device **10h**, drive spring **92h** is in a compressed (i.e., loaded) state, ready to bias the lancet **70h** to a puncturing position in skin-puncturing operation upon removal of an interference engagement.

[00166] Housing **12h** of lancet device **10h** comprises an elongated main body **20h** that generally has a cylindrical and hollow configuration. The main body **20h** has a distal or forward end portion **22h**, and a rear cap **24h** forming a proximal or rearward end portion **26h** of the main body **20h**. The interior of main body **20h** is generally open and defines an internal cavity **28h**. The internal cavity **28h** is closed at the rearward end due to the presence of rear cap **24h** and includes a front opening **30h** defined in forward end portion **22h** of main body **20h**, and through which lancet **70h** extends when lancet device **10h** is actuated. Main body **20h** and rear cap **24h** may be integrally formed. Typically, main body **20h** and rear cap **24h** are separate elements that are affixed together to form housing **12h**, as illustrated, which facilitates assembly of lancet device **10h**. As examples, main body **20h** and rear cap **24h** may be affixed together through an appropriate medical grade adhesive, and/or may be connected using inter-engaging structures providing a mechanical engagement therebetween, such as a friction-fit or a snap-fit construction. For example, main body **20h** may comprise an annular rim **32h** that cooperates with an annular rim **36h** on rear cap **24h** and which is recessed to accept annular rim **32h**. An adhesive, such as a medical grade adhesive, may be used to secure annular rim **32h** with annular rim **36h**. As with lancet devices **10d**, **10f**, and **10g**, distal or forward end portion **22h** of main body **20h** comprises an axially rearward-extending sleeve **96h** which defines a distal end pocket **98h** for receiving and supporting retraction spring **94h**.

[00167] Additionally, main body **20h** of housing **12h** further comprises a pivoting actuation structure or actuator **206** in a generally analogous manner to lancet device **10d** described previously, for causing actuation of lancet **70h** and corresponding release of drive spring **92h**. Actuation structure or actuator **206** generally comprises an actuating lever **208** that is pivotally movable relative to main body **20h**, and is desirably located at the rear end portion **26h** of main body **20h** proximate to rear cap **24h**. Actuating lever **208** may extend distally or forward from rear cap **24h** and be connected to rear cap **24h** by a living hinge or equivalent structure. Lever **208** may thus be integrally formed with rear cap **24h**. The lever **208** may alternatively be associated with main body **20h**. For example, lever **208** may be formed as part of the rear end portion **26h** of main body **20h**, or even formed as part of the forward end portion **22h** of main body **20h** and extend rearward or proximally toward rear cap **24h**. In contrast to previous embodiments, lever **208** comprises two opposed and

depending sidewalls 210. Sidewalls 210 terminate with a cutting edge or blade 212. Cutting edge 212 may be an integral, sharp edge on sidewalls 210 or be provided as a separate cutting blade secured to the ends of sidewalls 210. Lever 208 is generally adapted to be depressed into the internal cavity 28h of main body 20h so that cutting edges 212 may cut or sever an interfering engagement within in main body 20h restraining drive spring 92h, and thereby cause actuation of lancet device 10h as described in detail herein.

[00168] Main body 20h of housing 12h may be formed with a generally rectangular cross-section as illustrated in FIG. 46 and comprise opposing inner sidewalls 213 each defining an internal shelf or ledge 214. Lancet 70h is generally adapted to engage shelves 214 for restraining compressed drive spring 92h and, upon depression of lever 208 into main body 20h, a structure on lancet 70h is cut or severed to release the interference engagement of lancet 70h with shelves 214 and, thus, release the biasing force of drive spring 92h. Main body 20h defines a main guide channel 216 that accommodates lancet 70h and guides movement of lancet 70h within main body 20h.

[00169] Lancet 70h is formed in a generally analogous manner as previous embodiments and comprises a lancet 72h with a puncturing end 74h at the forward end thereof, and a carrier body 76h supporting lancet 72h at the rearward end thereof. The carrier body 76h now comprises a pair of outward extending tab members 218 which generally take the place of the guide tabs discussed previously in this disclosure. Tab members 218 are adapted for interference engagement with shelves 214 for positioning lancet 70h in housing 12h and main body 20h in particular. The interference engagement between tab members 218 and shelves 216 further serves to restrain compressed drive spring 92h. Tab members 218 are adapted to be cut or severed by cutting edge 212 on sidewalls 210 upon depression of lever 208 into main body 20h. For this purpose, tab members 218 may define a tapered cross-section forming a narrow neck or weakened area 220 which may be cut through by cutting edge 212 on sidewalls 210. Neck area 220 may take other forms, such as a score line, but is generally adapted to be easily cut or sheared through (i.e., cause failure of) by cutting edge 212 when lever 208 is depressed into main body 20h of housing 12h. Carrier body 76h further comprises a proximal or rearward end spring guide 86h and a distal or forward end spring guide 88h for engaging drive spring 92h and retraction spring 96h, respectively, of lancet device 10h. Spring guides 86h, 88h may be formed integral with the body of carrier body 76h or be provided as distinct, separate elements and secured to the body of carrier body 76h in the manner described previously.

[00170] In operation, lancet **70h** is adapted for axial movement through the main guide channel **216** of main body **20h** between an initial position wherein tab members **218** are in interference engagement with shelves **214** defined by main body **20h** and the puncturing end **74h** of lancet **72h** is disposed entirely within main body **20d**, to a puncturing position wherein carrier body **76h** is disposed in main guide channel **216** with the puncturing end **74h** extending beyond front opening **30h** of main body **20h** a sufficient distance to cause a puncture wound in a patient's body. In the initial, pre-actuated state of lancet device **10h**, drive spring **92h** is at least partially compressed between rear cap **24h** and carrier body **76h** and typically has sufficient stored potential energy to conduct a skin-piercing procedure. The rearward or proximal end of drive spring **92h** is typically secured to rear cap **24h** in the manner discussed previously in this disclosure. The forward or distal end of drive spring **92h** is associated with carrier body **76h** and disposed about proximal spring guide **86h**, and may be secured to carrier body **76h** by similar means discussed previously, as by suitable adhesive or direct mechanical attachment. As shown, for example, in FIG. 47, drive spring **92h** directly engages carrier body **76h**, and the carrier body **76h** may further comprise two outward-extending tabs or flanges **222** against which the forward end of drive spring **92h** is engaged to provide additional surfaces for transmitting the biasing force of drive spring **92h** to lancet **70h** to move the lancet **70h** to the puncturing position.

[00171] With continued reference to FIGS. 44-52, use and operation of lancet device **10h** will now be discussed. As with previous embodiments, a cover (not shown) extending distally from carrier body **76h** may be provided with carrier body **76h**. As with previous embodiments, such a cover would be removed by breaking the frangible connection with carrier body **76h** and withdrawing the cover from front opening **30h** in main body **20h**. Forward end rim **42h** of main body **20h** may then be placed in contact with the target location on the patient's body. As indicated previously, lancet device **10h** is initially provided in an armed state, with lancet **70h** ready to initiate a puncturing procedure when compressed drive spring **92h** is released.

[00172] To carry out a puncturing procedure, the user grasps opposing sides of housing **12h** and exerts downwardly directed force in the direction of Arrow **X** on lever **208**, causing lever **208** to pivot (i.e., depress) into internal cavity **28h** of main body **20h**. As lever **208** is depressed into main body **20h**, depending sidewalls **210** and, more particularly, cutting edge **212** at the end of each depending sidewall **210** contacts tab members **218** at the reduced cross-sectional, weakened area **220** on tab members **218**. As the lever **208** is continued to be depressed into main body **20h**, cutting edge **212** on sidewalls **210** begins to cut through the

neck area 220 on each tab member 218. Once the tab members 218 are completely cut-through, the interference engagement between tab members 218 and shelves 214 defined by sidewalls 213 of main body 20h is removed, releasing the drive spring 92b to bias lancet 70h to the puncturing position. With the biasing force of drive spring 92h released, drive spring 92h thereafter biases the lancet 70h away from rear cap 24h and through main guide channel 216. The biasing force imparted to lancet 70h is preferably sufficient to cause the puncturing end 74h of lancet 72h to project a sufficient distance and with sufficient force from the front opening 30h in main body 20h to cause a puncture wound in the desired location on the patient's body. Moreover, during the propelling movement of lancet 70h, proximal spring guide 86h on carrier body 76h releases from drive spring 92h which remains connected to rear cap 24h.

[00173] As the lancet 70h moves forward in the propelling movement, distal spring guide 88h engages retraction spring 94h. The biasing/propelling force provided by drive spring 92h is at least in part applied to retraction spring 94h by engagement of distal spring guide 88h with retraction spring 94h, which causes the retraction spring 94h to compress toward distal end pocket 98h. The retraction spring 94h permits puncturing end 74h of lancet 72h to extend through front opening 30h in main body 20h a sufficient distance and with sufficient force to puncture the skin of the patient and initiate blood flow, and thereafter return lancet 70h to a substantially fixed and stationary position within housing 12h. Carrier body 76h is desirably formed with a shoulder 224 formed at the base of distal spring guide 88h, and which is configured to engage an abutment surface or stop 226 defined by sidewalls 213 of main body 20h in main guide channel 216 to prevent lancet 70h from axial movement entirely out of main body 20h through front opening 30h. The stop 226 is defined rearward of rearward-extending internal sleeve 96h supporting retraction spring 94h. As the retraction spring 94h returns to a relaxed or unloaded state within main body 20h, the lancet 70h is retracted in main body 20h and returned to a substantially fixed and stationary positioned within main body 20h. Thereafter, the engagement of retraction spring 94h with distal spring guide 88h maintains the lancet 70h shielded within housing 12h, and prevents further movement of lancet 70h to the puncturing position, in the manner discussed in detail previously. In this disclosure, various elements have been identified as being adapted to be "cut", "sheared", "yielded", "fractured" to cause release and actuation of lancet device 10. These terms may all be grouped under a common heading of a "failure" item or element which is intended to fail when force is applied thereto in whatever form, for example blunt force or a cutting force.

[00174] Referring to FIGS. 53-55, a modification to a lancet device disclosed in United States Patent Application Serial No. 11/270,330, filed November 30, 2004, and entitled "Contact Activated Lancet Device", the entire disclosure of which is incorporated herein by reference, is shown. Lancet device **10** disclosed in the foregoing incorporated reference document may include a modified version of a retaining hub **90i**. FIG. 53 shows the retaining hub **90i** as part of the lancet device **10** disclosed in the incorporated reference document, the disclosure of which will be used to describe the location and operation of retaining hub **90i**. Retaining hub **90i** generally defines an annular shape and is adapted to maintain the lancet **70** in an initial armed position retracted within housing **12**. Retaining hub **90i** typically includes two opposed and elongated support members **91i** connected by two pivotal cam elements **92i** to form the annular shape of retaining hub **90i**. Cam elements **92i** each include two outward-extending shafts **93i** engaged pivotally with the opposed support members **91i**. Cam elements **92i** each further include at least one typically wedge-shaped contact element **94i** defining an upper contact surface **96i** on the upper surface thereof. Cam elements **92i** each further define a generally centrally located recess or cut-out **100i** defined in a bottom side thereof. The purpose of recess **100i** is described herein in connection with the operation of retaining hub **90i** in lancet device **10**. As shown in FIGS. 54 and 55, the cam elements **92i** desirably each include two contact elements **94i** disposed generally at opposite ends of the cam elements **92i**, with the recess **100i** defined in the bottom side of the cam elements **92i** between the contact elements **94i**.

[00175] In lancet device **10**, retaining hub **90i** and lancet **70** are in interference engagement with each other, such that retaining hub **90i** retains the lancet **70** in an initial armed state retracted within housing **12**. For example, fingers **82** on carrier element **76** may rest on the upper side of cam elements **92i**, thereby providing interference engagement between the lancet **70** and the retaining hub **90i**. Moreover, upper contact surface **96i** on the contact elements **94i** may be adapted for contacting engagement with structure within housing **12**. For example, rear cap **24** of housing **12** may include structure extending therein, such as internal contact **46** integrally formed and extending on at least one, and desirably on two opposing inner sidewalls thereof. As retaining hub **90i** typically includes two contact elements **94i** on each cam element **92i**, two internal contacts **46** may be provided on each of the two opposing inner sidewalls of the housing **12**. Each internal contact **46** includes a distal engagement cam surface **47** for contacting engagement with the corresponding contact surface **96i** on contact elements **94i**.

[00176] During usual operation of the lancet device **10**, axial movement of shield body **50** toward rear cap **24**, causes the retaining hub **90i** to be displaced rearwardly toward rear cap **24**, with fingers **82** of the carrier element **76** resting upon the cam elements **92i**. Such rearward movement of retaining hub **90i** causes the contact surfaces of engagement cam surfaces **47** of the internal contacts **46** within rear cap **24** to engage and co-act with the corresponding contact surfaces **96i** on the contact elements **94i** of cam elements **92i**. Such engagement and continued downward movement of internal contacts **46** causes the cam elements **92i** to pivot on or rotate about shafts **93i** with respect to support members **91i**. Due to the generally wedge-shaped profile of the contact elements **94i**, the pivotal movement of cam elements **92i** has the effect of further compressing drive spring **102** by further “lifting” fingers **82**, at least until the point where rear nub **86** on carrier element **76** contacts the inner side of rear cap **24**. At this point, continued axial displacement of shield body **50** toward rear cap **24** pivots cam elements **92i** to a position where recess **100i** defined in the bottom side of cam elements **92i** has rotated to a position generally aligned with fingers **82** at which point the interference engagement between fingers **82** and cam elements **92i** is released by such alignment. The biasing force of drive spring **102** then propels lancet **70** downward away from the rear cap **24** axially through housing **12** and shield body **50**, with guide tabs **78** passing axially through the annular opening defined by retaining hub **90i**.

[00177] Referring to FIGS. 56-67, a final embodiment of a lancet device **10k** is generally shown. Lancet device **10k** generally includes a housing **12k**, a shield **14k** movably associated with the housing **12k**, and a lancet **70k** movably disposed in housing **12k**. Shield **14k** is movably associated with housing **12k**, and is at least partially disposed within housing **12k**. Shield **14k** extends outward from housing **12k**, while the lancet **70** is contained within housing **12k** and is typically axially movable through the shield **14k**.

[00178] Housing **12k** comprises an elongated main body **20k** having a generally cylindrical and hollow configuration. Main body **20k** has a distal or forward end portion **22k**, and a rear cap **24k** forming a proximal or rearward end portion **26k** of the main body **20k**. The interior of main body **20k** is generally open and comprises an internal cavity or bore **28k**. The internal cavity **28k** is closed at the rearward end due to the presence of rear cap **24k**, and includes a front opening **30k** defined by forward end portion **22k** of main body **20k**, and through which shield **14k** extends. Main body **20k** and rear cap **24k** may be integrally formed. Alternatively, main body **20k** and rear cap **24k** may be separate elements that are affixed together to form housing **12k** in the general manner described previously in

this disclosure. Main body **20k** further includes a forward rim **42k** formed as part of forward end portion **22k** and which defines front opening **30k**.

[00179] Shield **14k** is typically a generally cylindrical, hollow structure comprising a shield body **50k** having a distal or forward end **52k** and a proximal or rearward end **54k**, and defines an internal cavity or bore **56k** extending therethrough. Forward end **52k** of shield body **50k** defines a partial forward end wall or rim **58k** defining a forward opening **60k**, through which a puncturing element of lancet **70k** extends when lancet device **10k** is actuated by a user. Forward end wall **58k** typically defines a small contact area about forward opening **60k** for contacting an intended puncture area on a patient's body. The reduced contact area may be made smaller (i.e., reduced in surface area) by providing a plurality of peripheral indentations (not shown) formed perimetrically in shield **14k**. The external surface features of housing **12k** and shield **14k** may be formed in accordance with the ergonomic features and structure disclosed in application Serial No. 11/123,849 incorporated by reference previously in this disclosure. Rearward end **54k** of shield body **50k** defines a rear rim **63k**.

[00180] Shield **14k** is typically axially and slidably movable within housing **12k**. Shield **14k** and housing **12k** may be coaxially associated, with shield **14k** and housing **12k** coaxially disposed around a common Central Axis A. Shield **14k** and housing **12k** may each be generally cylindrical-shaped. A rotation element or cam follower, typically a guide plate **262** is further associated with shield **14k**. In particular, guide plate **262** is disposed at the rearward end **54k** of shield body **50k** and engages rear rim **63k** of shield body **50k**. Plate **262** is a generally annular-shaped structure and defines a central opening **263** with two opposed clearance slots **264** and two opposed guide slots **266**. Clearance slots **264** and guide slots **266** are orientated along axes that are generally orthogonal to one another. An outer periphery or perimeter of plate **262** is formed with two opposed cam guide recesses **268** for receiving and engaging a cam structure adapted to cause rotation of plate **262** to cause actuation of lancet device **10k** as described further herein. Plate **262** is typically in rotational sliding engagement or contact with rear rim **63** of shield body **50k** to permit rotation thereof relative to rear rim **63**. In particular, plate **262** comprises a bottom side **270** in contact with rear rim **63k** and an upper side **272** facing away from rear rim **63k**. Due to the contact between the bottom side **270** of plate **262** and rear rim **63**, plate **262** is adapted to slide together with shield body **50k** in main body **20k** when axial motion is imparted to shield body **50k**, for example by axially retracting (i.e., depressing) shield body **50k** into main body **20k** to actuate lancet device **10k** as described herein. Accordingly, any axial motion applied to shield body



**50k** to retract (i.e., depress) shield body **50k** into main body **20k** of housing **12k** will be transmitted to plate **262** through the contact engagement of rear rim **63k** and plate **262**.

[00181] Lancet device **10k** further comprises a lancet **70k** disposed within the housing **12k**, and extending into shield **14k**. Lancet **70k** includes a puncturing element shown in the form of a lancet **72k**. Lancet **72k** comprises a puncturing end **74k** at the forward end thereof. Lancet **70k** is generally adapted for axial movement through the internal cavity **56k** of shield body **50k** between an initial position, wherein the puncturing end **74k** is disposed within shield body **50k**, to a puncturing position wherein the puncturing end **74k** extends beyond the forward opening **60k** of shield body **50k** a sufficient distance to cause a puncture wound in a patient's body. The puncturing end **74k** of lancet **72k** is adapted for puncturing the skin of a patient, and may be in the form of a pointed end, needle tip, blade edge, and the like. Puncturing end **74k** may include a preferred alignment orientation, such as with a pointed end or a blade aligned in a specific orientation. In such an orientation, shield body **50k** and/or main body **20k** of housing **12k** may include target indicia corresponding to the alignment orientation of puncturing end **74k**. Indentations (not shown) in the shield body **50k** and/or indentations (not shown) in main body **20k** may function as such an alignment orientation, as described previously in this disclosure.

[00182] Lancet **70k** comprises a carrier body **76k** supporting lancet **72k** at the rearward end thereof. Carrier body **76k** and shield body **50k** may include corresponding guiding surfaces for guiding the movement of lancet **70k** in shield body **50k**. For example, carrier body **76k** may include guide tabs **78k** on an external surface thereof, with shield body **50k** defining corresponding guide channels **80k** extending longitudinally along an inner wall thereof for accommodating guide tabs **78k** slidably therein upon actuation of lancet device **10k**. Carrier body **76k** may include a pair of elongated guide tabs **78k** on opposing lateral sides thereof as illustrated, or a single elongated guide tab **78k**, and shield body **50k** may include a corresponding pair of guide channels **80k** extending along opposing inner surfaces thereof corresponding to each of the guide tabs **78k**, or a single corresponding guide channel **80k**. The engagement of guide tabs **78k** in guide channels **80k** in the initial, pre-actuated state of lancet device **10k** ensures that lancet **70k** is prevented from substantial rotation in shield body **50k** during the actuation sequence of lancet device **10k**, wherein plate **262** is set into sliding rotational movement relative to rear rim **63k** as described herein. Upon actuation, engagement of guide tabs **78k** in guide channels **80k** guides movement of lancet **70k** to the puncturing position.

[00183] As shown in FIG. 60, in addition to two opposed guide tabs **78k**, carrier body **76k** further comprises two actuation tabs **81k** oriented along an axis generally orthogonal to an axis passing through guide tabs **78k**. Actuation tabs **81k** form part of the actuation structure or actuator of lancet device **10k**. Actuation tabs **81** are shorter in length than guide tabs **78k**, which typically extend approximately the length of carrier body **76k**. Actuation tabs **81k** comprise a distal facing surface **82k** adapted to engage or rest upon the upper side **270** of guide plate **262** in the initial, pre-actuated state of lancet **70k**. Actuation tabs **81k** are generally adapted to mate or align with clearance slots **264** in plate **262** when plate **262** is rotated to the appropriate alignment position with actuation tabs **81k** to allow actuation of lancet device **10k** as described herein. Likewise, guide tabs **78k** are sized to mate with guide slots **266** in plate **262**. However, guide tabs **78k** generally extend at least partially through guide slots **266** in the initial, pre-actuated state of lancet device **10k**, and the guide slots **266** are typically sized larger enough to allow plate **262** to rotate relative to carrier body **76k** without guide tabs **78k** interfering with such rotation due to their presence in guide slots **266**.

[00184] Shield body **50k** may define additional internal guide channels **84k** for receiving actuation tabs **81k** when the interference engagement between actuation tabs **81k** and plate **262** is removed by rotation of plate **262**. Such additional guide channels **84k** are optional as the association of guide tabs **78k** and guide channels **84k** is typically sufficient to guide the movement of carrier body **76k** during the puncturing movement of lancet **70k**. If provided, additional guide channels **84k** may extend the internal length of shield body **50k** or along only a portion of the length of shield body **50k**. Carrier body **76k** further comprises a proximal or rearward end spring guide **86k** and a distal or forward end spring guide **88k** for engaging a drive spring and retraction spring, respectively, of lancet device **10k** as described herein. Spring guides **86k**, **88k** may be formed integral with the carrier body **76k** or be provided as distinct, separate elements in the manner described previously in this disclosure.

[00185] Movement of the lancet **70k** through the lancet device **10a** is achieved through a biasing force provided by a drive spring **92k**. Drive spring **92k** is adapted to exert a biasing force against lancet **70k** to drive lancet **70k** through lancet device **10k** toward the puncturing position, and is disposed between the rearward end of main body **20k** and the lancet **70k**. Rear cap **24k** may include structure for alignment of and/or for maintaining drive spring **92k** in the proper orientation on rear cap **24k**. For example, rear cap **24k** may include an internal alignment structure (not shown) for correctly positioning the drive spring **92k**. Lancet **70k**, as indicated previously, includes proximal spring guide **86k** which engages the opposite end of drive spring **92k** in the initial or pre-actuated state of lancet device **10k**. Guide tabs **78k**

and actuation tabs **81k** may be used as additional or replacement structure for engaging the distal end of drive spring **92k**.

[00186] In the initial state of lancet device **10k**, drive spring **92k** is typically in a generally uncompressed, unloaded state between rear cap **24k** and distal spring guide **86k** of carrier body **76k**. However, drive spring **92k** may exert a limited forward biasing or positioning force on carrier body **76k** via proximal spring guide **86k** to help maintain the interference engagement between actuation tabs **81k** and plate **262**. Alternatively, drive spring **92k** may be partially compressed between rear cap **24k** and carrier body **76k** and is adapted for further compression therebetween. During actuation of lancet device **10k**, the retraction of shield body **50k** into main body **20k** causes compression or further compression of drive spring **92k** due to the interference engagement between lancet **70k** and plate **262**, thereby storing potential energy in drive spring **92k** necessary to bias lancet **70k** to the puncturing position. As shield body **50k** is further retracted into main body **20k**, the rotation of plate **262** relative to lancet **70k** eventually removes the interference engagement between actuation tabs **81k** and plate **262**, thereby releasing the potential energy stored in compressed drive spring **92k** as kinetic energy applied to lancet **70k** to bias lancet **70k** to the puncturing position.

[00187] A retraction or return spring **94k** may further be provided at the forward end of the lancet device **10k**, for retracting the lancet **70k** within shield body **50k** after lancet **70k** has moved axially to the puncturing position wherein puncturing element **74k** extends outward from the distal or forward end **52k** of shield body **50k**. Retraction spring **94k** is adapted to be engaged by distal spring guide **88k** extending forward from carrier body **76a** during the forward, puncturing movement of lancet **70k**, as described herein. The forward end wall **58k** of shield body **50k** forms a distal end pocket **98k** for receiving and supporting retraction spring **94k**. Retraction spring **94k** is disposed in distal end pocket **98k** throughout the operation sequence of lancet device **10a** in a puncturing procedure. Retraction spring **94k** may be secured to the internal side of the forward end wall **58k** of shield body **50k** through use of a medical grade adhesive or by mechanically securing retraction spring **94k** thereto in the manner described previously in this disclosure. Drive and retraction springs **92k**, **94k** are typically compression springs capable of storing potential energy when in a compressed state. Lancet device **10k** may further include a protective tab or cover **100k** for protectively covering the forward end of the lancet **70k** as described in previous embodiments. The respective elements of the lancet device **10k** are all typically formed of molded plastic material, such as a medical grade plastic material. Lancet **72k** may be constructed of any

suitable material adapted for puncturing the skin, and is typically a surgical grade metal such as stainless steel.

[00188] Rear cap 24k of housing 12k further comprises internal structure adapted to interact with plate 262 to cause actuation of lancet device 10k. In particular, rear cap 24k is formed with at least one and typically two distally-extending actuation members typically cam elements 280 each having a tapered cam surface 282 formed on their distal ends. Cam elements 280 are formed to extend distally into the respective cam guide recesses 268 in plate 262. The cam interaction between cam elements 280 and plate 262 provides the means by which the interference engagement between the lancet 70k and plate 262 is removed to allow lancet 70k to move to the puncturing position. More particularly, the interaction between the tapered cam surfaces 282 on cam elements 280 and cam guide recesses 268 in plate 262 during the retracting movement of shield body 50k into main body 20k causes sufficient rotational movement of plate 262 relative to carrier body 76k to allow actuation tabs 81k to align with clearance slots 264 in plate 262 to remove the interference engagement between lancet 70k and plate 262. As indicated previously, such rotational movement of plate 262 is sliding rotational movement on rear rim 63k of shield body 50k. Also as indicated previously, guide slots 266 in plate 262 are preferably sized sufficiently to allow plate 262 to rotate to the alignment position without guide tabs 78k interfering with such rotation.

[00189] Due to the elongated length of cam elements 280, shield body 50k defines opposed cut-outs or notches 284 to accommodate the distal tips of cam elements 280 extending through cam guide recesses 268 in the initial, pre-actuated state of lancet device 10k, and the eventual forward position of the distal tips of cam elements 280 as shield body 50k is retracted into main body 20k to cause actuation of lancet device 10k. Cam guide recesses 268 are initially offset from notches 284 but as plate 262 is rotated to the alignment position cam guide recesses 268 eventually align with notches 284 as shown in FIG. 62. The engagement of cam elements 280 with plate 262 in cam guide recesses 268 provides an additional advantage of maintaining or locking the orientation of plate 262 on rear rim 63k of shield body 50k. Thus, plate 262 will be prevented or inhibited from disengaging from and falling off of rear rim 63k should lancet device 10k be turned upside down (i.e., shield 14k pointed upward) prior to use. Additional structure extending from rear cap 24k or internally from the inner wall of main body 20k of housing 12k may be provided to maintain the positioning of plate 262 on rear rim 63k of shield body 50k.

[00190] Additionally, in order to prevent the possibility of rotational motion imparted to plate 262 by cam elements 280 from being transmitted to shield body 50k, shield body 50k

may comprise longitudinally-extending outer ribs **288** which are adapted to cooperate with interfering structure on the inner wall of main body **20k**, such as an engaging tab or detent (not shown). The engagement of such a tab or detent with ribs **288** will substantially lock the orientation of shield body **50k** relative main body **20k** and prevent rotation of shield body **50k** relative to main body **20k**. Moreover, engagement ribs **288** may be used as guiding structure to guide the retracting movement of shield body **50k** into main body **20k** during actuation of lancet device **10k**. Shield body **50k** further defines an abutment shoulder **290** at forward end **52k**. Abutment shoulder **290** is adapted for interference engagement with forward rim **42k** of main body **20k** to prevent shield body **50k** and, thus, lancet **70k** from axial forward movement out of main body **20k** through front opening **30k**. Additionally, the limited positioning or biasing force of drive spring **92k** on lancet **70k** in the initial, pre-actuated state of lancet device **10k** is transmitted by the interference engagement between plate **262** and shield body **50k** to shoulder **290**, which then engages forward rim **42k**.

[00191] Use and actuation of lancet device **10k** will now be described with continued reference to FIGS. 56-67. Lancet device **10k** is typically initially provided with cover **100k** extending distally from carrier body **76k**, and through forward opening **60k** in forward end wall **58k** of shield body **50k**. In the initial, pre-actuated state of lancet device **10k**, drive spring **92k** is typically uncompressed between the inner side of rear cap **24a** and proximal spring guide **86a** of carrier body **76a**, and lancet **70k** is initially in interference engagement with plate **262**, for example under the limited position or biasing force provided by drive spring **92k**. In particular, actuation tabs **81k** extending from carrier body **76k** rest upon the upper side **270** of plate **262** and are offset from mating clearance slots **264** in plate **262**. Further, in the initial, pre-actuated state of lancet device **10k**, guide tabs **78k** are disposed in guide channels **80** in shield body **50k**, and extend proximally through guide slots **266** in plate **262**. As indicated previously, the engagement of guide tabs **78k** in guide channels **80k** prevents rotation of lancet **70k** in shield body **50k** and, more particularly, carrier body **76k** in shield body **50k** during the rotational movement of plate **262** used to release the interference engagement between actuation tabs **81k** and plate **262**, as described herein. Cam elements **280** extending distally from rear cap **24k** extend at least partially through the respective cam guide recesses **268** defined in the periphery of plate **262**. Typically, the tapered cam surfaces **282** of cam elements **280** contact plate **262** within cam guide recesses **268** to allow cam elements **280** to effect the rotational movement of plate **262** when shield body **50k** is retracted (i.e., depressed) into main body **20k**, and secondarily to maintain plate **262** associated with rear rim **63k** of shield body **50k**. As described previously, guide slots **266** in

plate 262 are sized to accommodate guide tabs 78k and to allow plate 262 to rotate relative carrier body 76k without guide tabs 78k interfering with such rotational movement necessary to allow actuation tabs 81k into alignment with clearance slots 264 in plate 262. In this initial, pre-actuated state of lancet device 10k, cam guide recesses 268 are offset from notches 284 in shield body 50k with the only the distal tips of cam elements 280 extending through cam guide recesses 268 as shown in FIG. 65B.

[00192] To use the lancet device 10k, the user grasps opposing sides of housing 12k, such as between a finger and thumb, and removes breakable cover 100k. Cover 100k is removed typically by moving cover 100k in a combined twisting and pulling motion in forward opening 60k in forward end wall 58a of shield body 50k to break the frangible connection with carrier body 76k. Once the frangible connection is broken, cover 100k may be removed through the forward opening 60k. Forward end wall 58k of shield body 50k may then be placed in contact with a location on the patient's body where it is desired to cause a puncture injury to initiate blood flow. If provided, target indicia may be aligned with the desired location of puncture.

[00193] Once placed against the body, the user exerts a downwardly directed force on main body 20k of housing 12k forcing shield body 50k of shield 14k to retract (i.e., depress) into housing 12k. In particular, the user applies a downward directed force in the direction of Arrow X, thereby applying a force against the user's body (i.e., skin surface). Such force establishes an opposing force on forward end wall 58k of shield body 50k causing shield body 50k to retract axially within main body 20k of housing 12k. As shield body 50k retracts into main body 20k, rearward end 54k of shield body 50k moves proximally (i.e., rearward) toward rear cap 24k. The engagement between rear rim 63k at the rearward end 54k of shield body 50k and plate 262 causes plate 262 to move together with shield body 50k toward rear cap 24k. As the entire lancet 70k moves rearward due to the interference engagement between actuation tabs 81k and plate 262, drive spring 92k begins to compress or compresses further between rear cap 24k and carrier body 76k and, more particularly, between proximal spring guide 86k and rear cap 24. Substantially simultaneously, cam elements 280 interact with plate 262 in cam guide recesses 268 in plate 262, and act upon plate 262 to cause plate 262 to slidably rotate on rear rim 63 of shield body 50k. In particular, as shield body 50k moves proximally, tapered cam surfaces 282 on cam elements 280 engage plate 262 in cam guide recesses 268 causing plate 262 to rotate. The tapered form of tapered cam surface 282 converts the linear retraction motion imparted to shield body 50k to rotational movement of plate 262. The engagement of guide tabs 78k in guide

channels **80k** prevents lancet **70k** and carrier body **76k** in particular from rotating in shield body **50k**. As shown in FIG. 66B, the distal ends of cam elements **280** project further through cam guide recesses **268** as cam elements **280** rotate plate **262** toward the release position where actuation tabs **81k** align with clearance slots **264** in plate **262**.

[00194] As the entire lancet **70k** continues move rearward due to the interference engagement between actuation tabs **81k** and plate **262**, drive spring **92k** continues to compress between rear cap **24k** and proximal spring guide **86k**, and cam elements **280** continue to rotate plate **262** on rear rim **63k** of shield body **50k**. Eventually, plate **262** rotates to the release position where actuation tabs **81k** align with clearance slots **264** in plate **262**, as shown in FIG. 67B. When this occurs, the interference engagement between actuation tabs **81k** and plate **262** is released. At the moment the actuation tabs **81k** align with clearance slots **264**, the restraining force applied to drive spring **92k** due to the interference engagement between actuation tabs **81k** and plate **262** is released, releasing the stored potential energy in drive spring **92k** as kinetic energy used to move lancet **70k** forward in shield body **50k**. With the stored potential energy in compressed drive spring **92k** released as kinetic energy, drive spring **92k** biases lancet **70k** away from rear cap **24k** and through internal cavity **56k** in shield body **50k**. During such movement, corresponding guide tabs **78k** and guide channels **80k** guide lancet **70k** axially through shield body **50k**. The biasing force acting on lancet **70k** is preferably sufficient to cause the puncturing end **74k** of lancet **72k** to project a sufficient distance and with sufficient force from the forward opening **60k** in shield body **50k** to cause a puncture wound in the desired location on a patient's body. Moreover, during the propelling axial movement of lancet **70k**, proximal spring guide **86k** on carrier body **76k** of lancet **70k** releases from drive spring **92k** which remains connected to rear cap **24k**. In lancet device **10k**, lancet **70k** is limited to axial movement only with respect to shield **14k** and housing **12k**.

[00195] Moreover, as lancet **70k** moves forward in the propelling movement, distal spring guide **88k** engages the rearward end of retraction spring **94k**. The biasing force provided by drive spring **92k** is at least in part applied to retraction spring **94k** by engagement of distal spring guide **88k** with the rearward end of retraction spring **94a** which causes retraction spring **94k** to compress toward distal end pocket **98k** and store potential energy. Retraction spring **94k** is designed such that it may be compressed in whole or in part by the biasing force of drive spring **92k** propelling lancet **70k**, but still permits puncturing end **74k** of lancet **72k** to extend through forward opening **60k** in shield body **50k** a sufficient distance and with sufficient force to puncture the skin of the patient and initiate blood flow. Guide channels

**84k** associated with actuation tabs **81k** may be formed with abutment surfaces for engagement by actuation tabs **81k** during the forward movement of lancet **70k** to prevent lancet **70k** from axial movement entirely out of shield body **50k** through forward or front opening **60k**. Alternatively, carrier body **76k** and/or distal spring guide **88k** may be adapted for interference engagement with forward end wall **58** of shield body **50k** to prevent lancet **70k** from axial movement entirely out of shield body **50k** through forward or front opening **60k**

[00196] As indicated previously, retraction spring **94k** is typically a compression spring and will have sufficient resilience to return to a relaxed, unloaded state within shield body **50k** after the lancet **70k** extends to the puncturing position. Accordingly, once the retraction spring **94k** is compressed it will provide a return biasing force on the lancet **70k** by engagement with the distal spring guide **88k** on carrier body **76k**. Retraction spring **94k** thereby acts between the forward end wall **58k** of the shield body **50a** and distal spring guide **88k** on carrier body **76k** to cause complete retraction of lancet **70k** into shield body **50k**. In particular, retraction spring **94k** applies a return biasing force that retracts the puncturing end **74k** of lancet **72k** entirely within shield body **50k**. Moreover, as the retraction spring **94k** returns to a relaxed or unloaded state within shield body **50k**, lancet **70k** is returned to a static position within shield body **50k**, wherein lancet **70k** is disposed at a relatively fixed and stationary position within shield body **50**. Once retraction spring **94k** returns to a relaxed or uncompressed state, retraction spring **94k** maintains lancet **70k** disposed within the shield body **50k** with puncturing end **74k** shielded within shield body **50k**, and prevents further movement of lancet **70k** toward the puncturing position.

[00197] While the invention was described with reference to several distinct embodiments of the lancet device, those skilled in the art may make modifications and alterations to the invention without departing from the scope and spirit of the invention. Accordingly, the above detailed description is intended to be illustrative rather than restrictive. The invention is defined by the appended claims, and all changes to the invention that fall within the meaning and range of equivalency of the claims are to be embraced within their scope.



## THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. A lancet device, comprising:
  - a housing;
  - a lancet disposed in the housing and axially movable through the housing and comprising a puncturing element, the lancet adapted for axial movement between an initial position wherein the puncturing element is disposed within the housing and a puncturing position wherein the puncturing element extends through a front opening in the housing for a puncturing procedure;
  - a drive spring disposed between a rearward end of the housing and the lancet for biasing the lancet to the puncturing position, the drive spring held in an at least partially compressed state between the rearward end of the housing and the lancet by an interference engagement between the lancet and housing; and
  - an actuator pivotally connected to the housing and in contact engagement with the lancet in the initial position for causing release of the drive spring;
  - wherein movement of the actuator causes pivotal movement thereof into the housing causing at least a portion of the lancet to move downward in the housing until the lancet is released of interference engagement with the housing thereby releasing the at least partially compressed drive spring to bias the lancet through the housing to the puncturing position.
  
2. The lancet device of claim 1, wherein the lancet comprises at least one outward-extending guide tab and the housing defined an internal guide channel comprising a longitudinal main channel and a generally transverse side channel, and wherein the interference engagement comprises the guide tab engaging the intersection of the main channel and side channel.

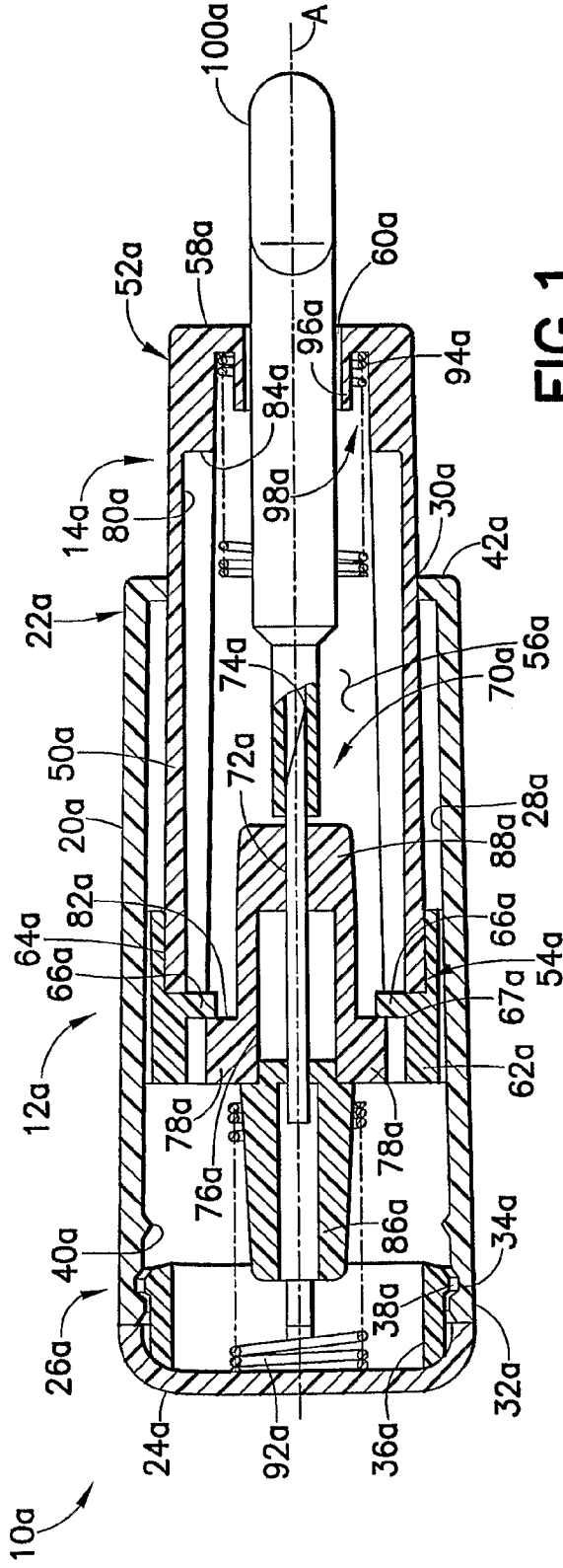


FIG. 1

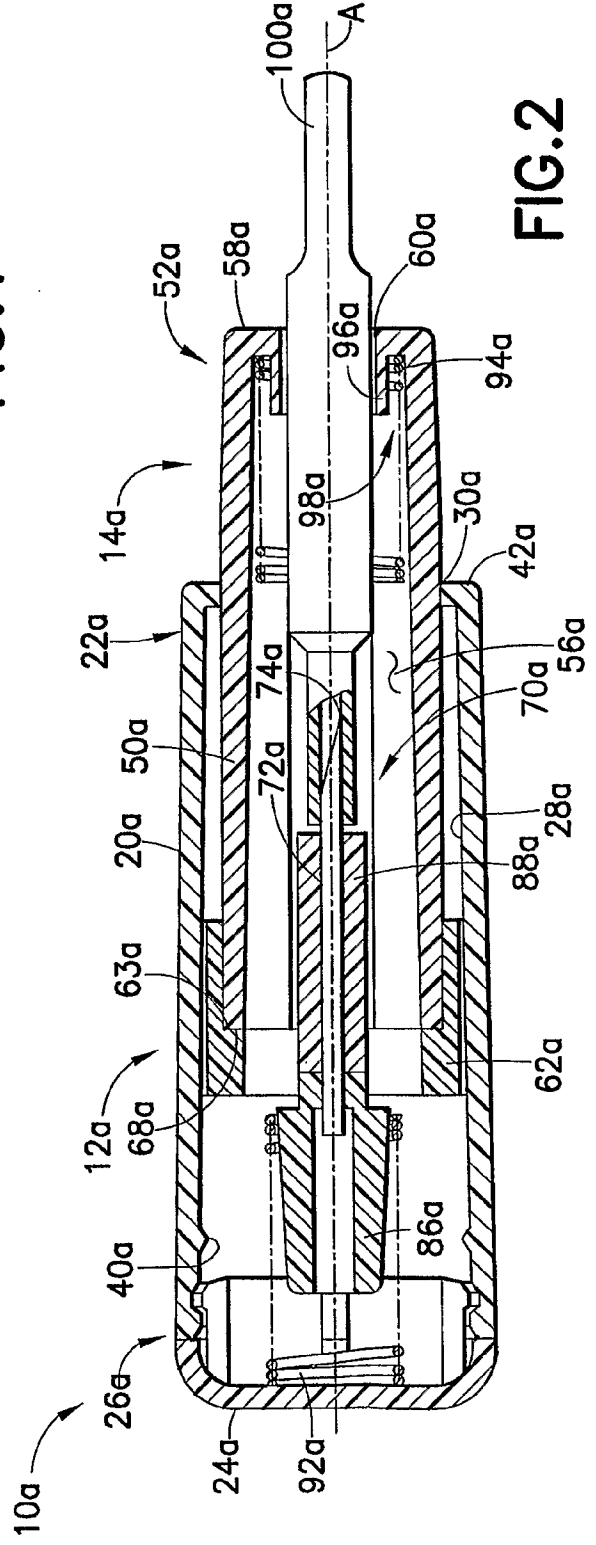


FIG. 2

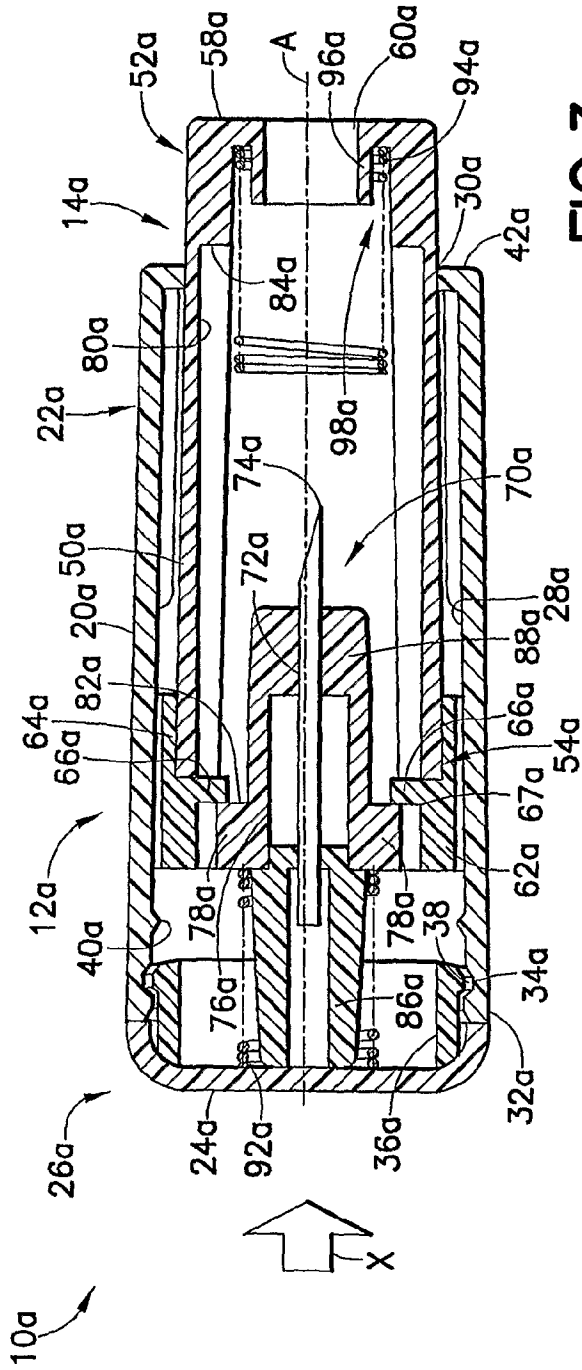


FIG. 3

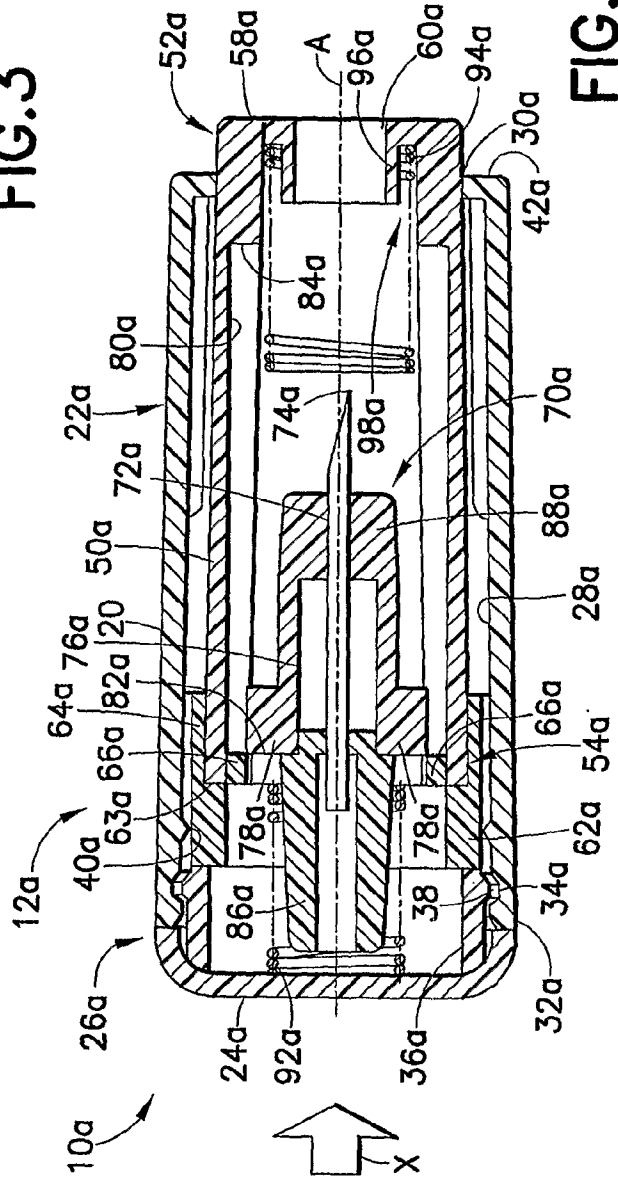


FIG. 4



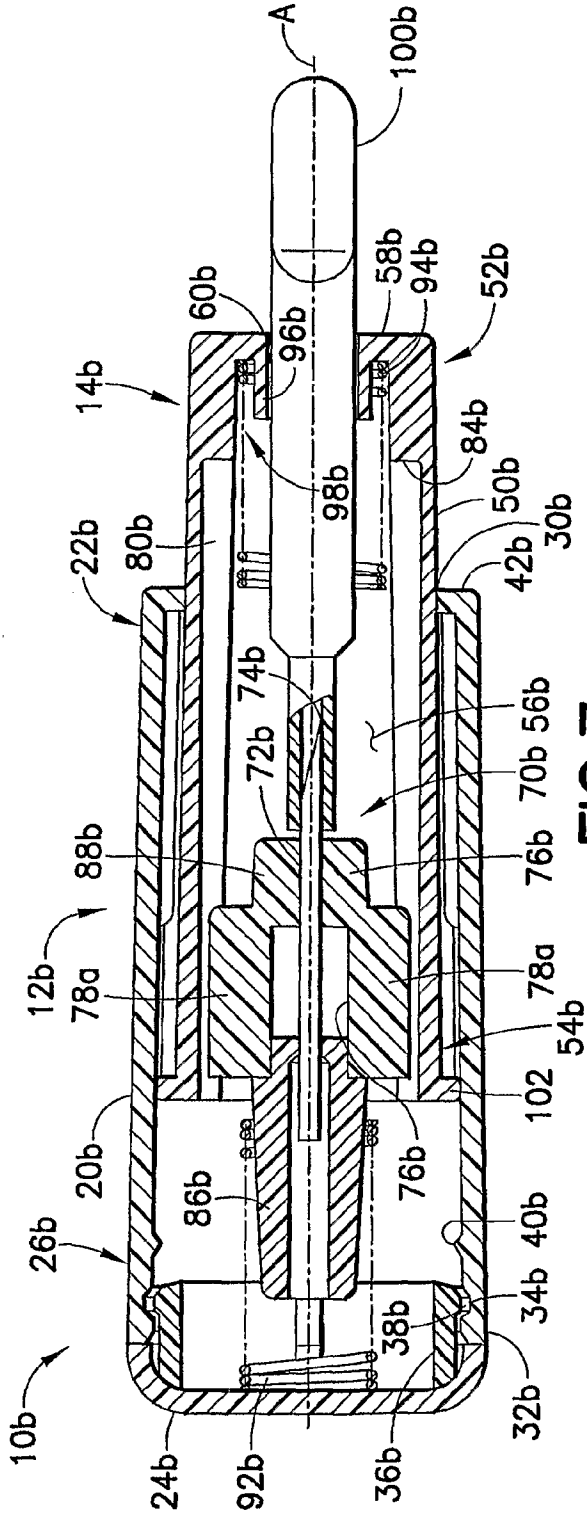


FIG. 7

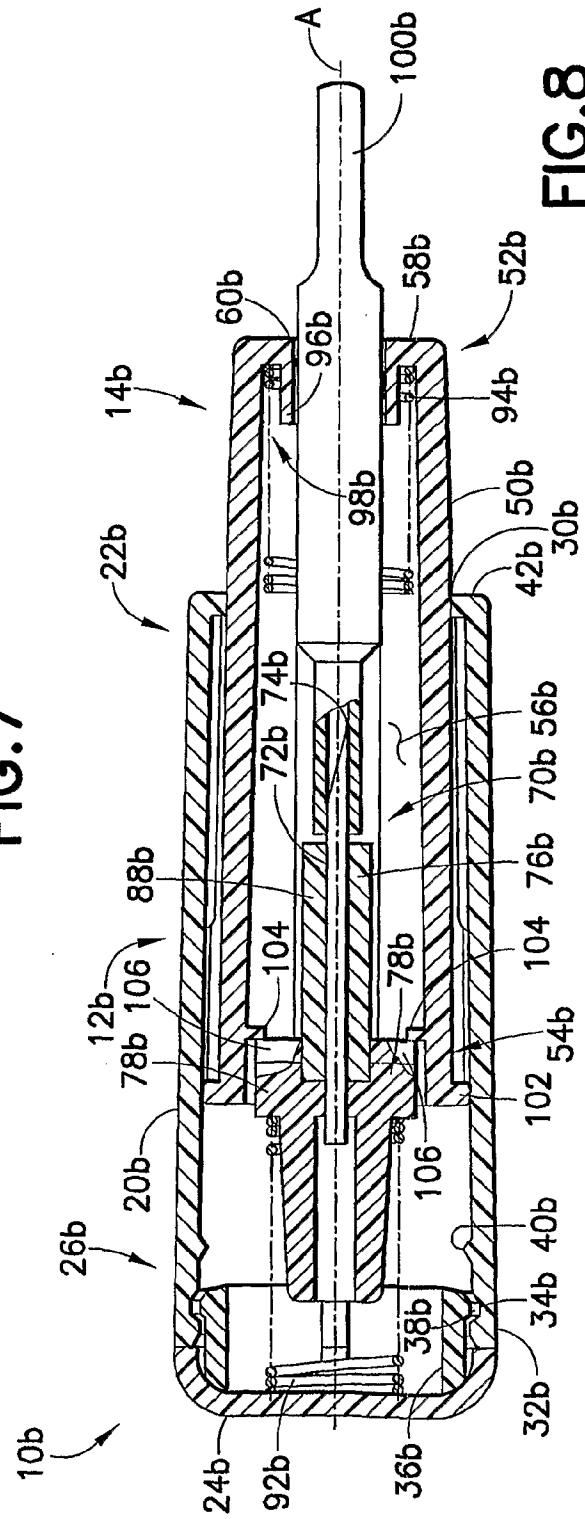


FIG. 8

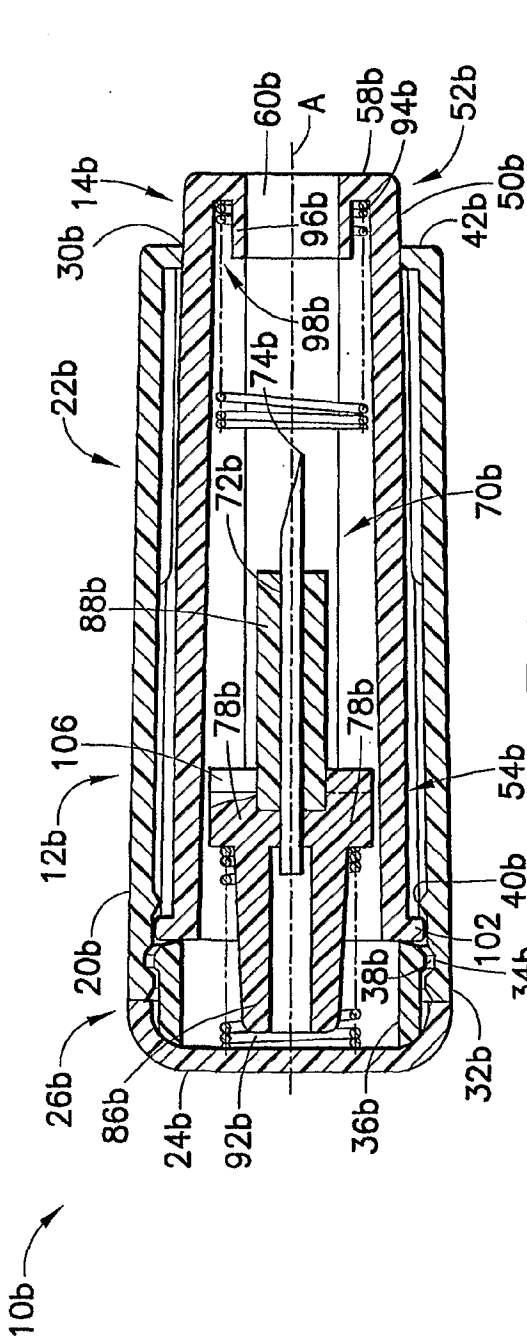


FIG. 9

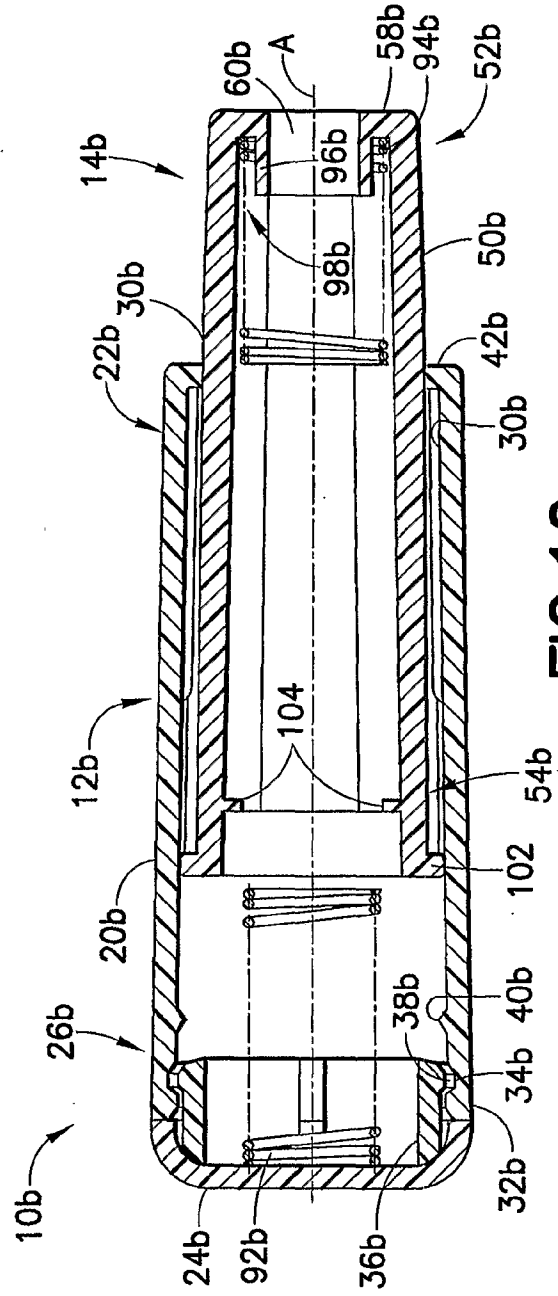


FIG. 10

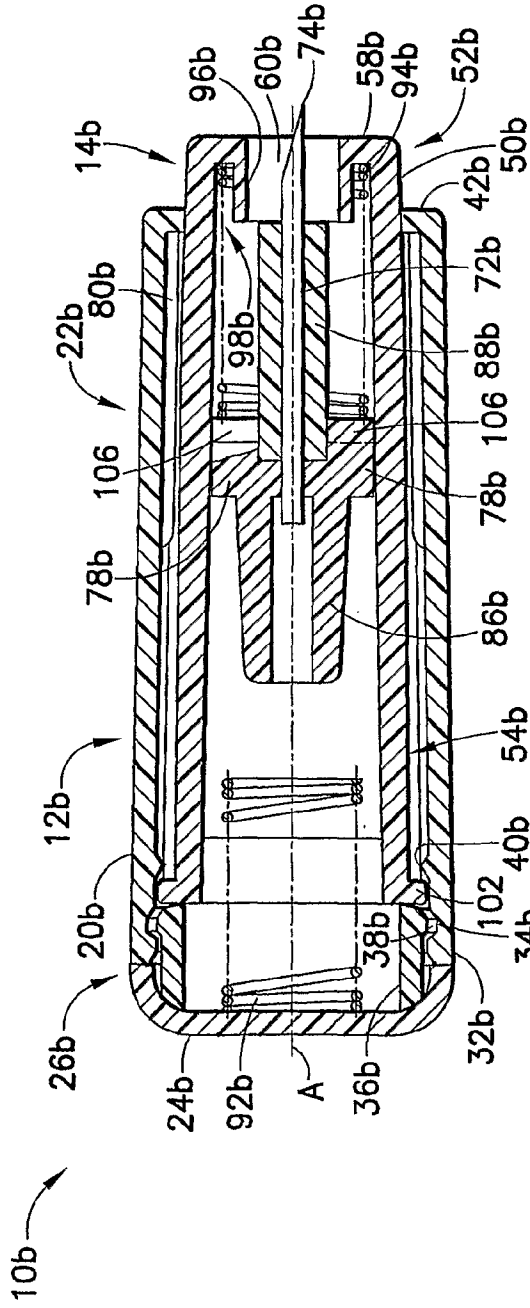


FIG. 11

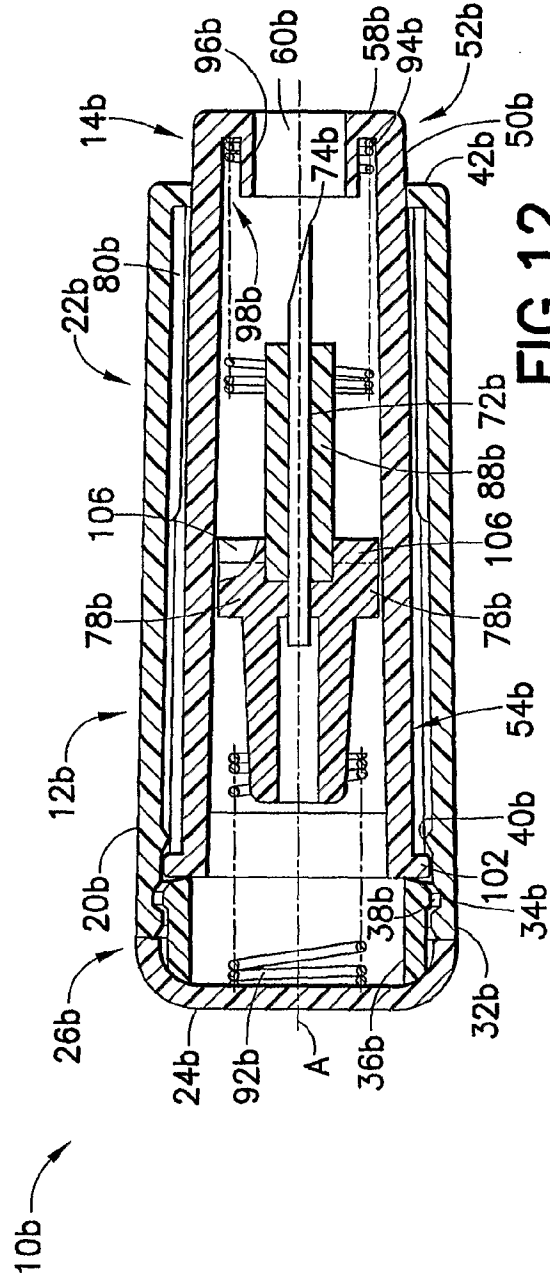


FIG. 12

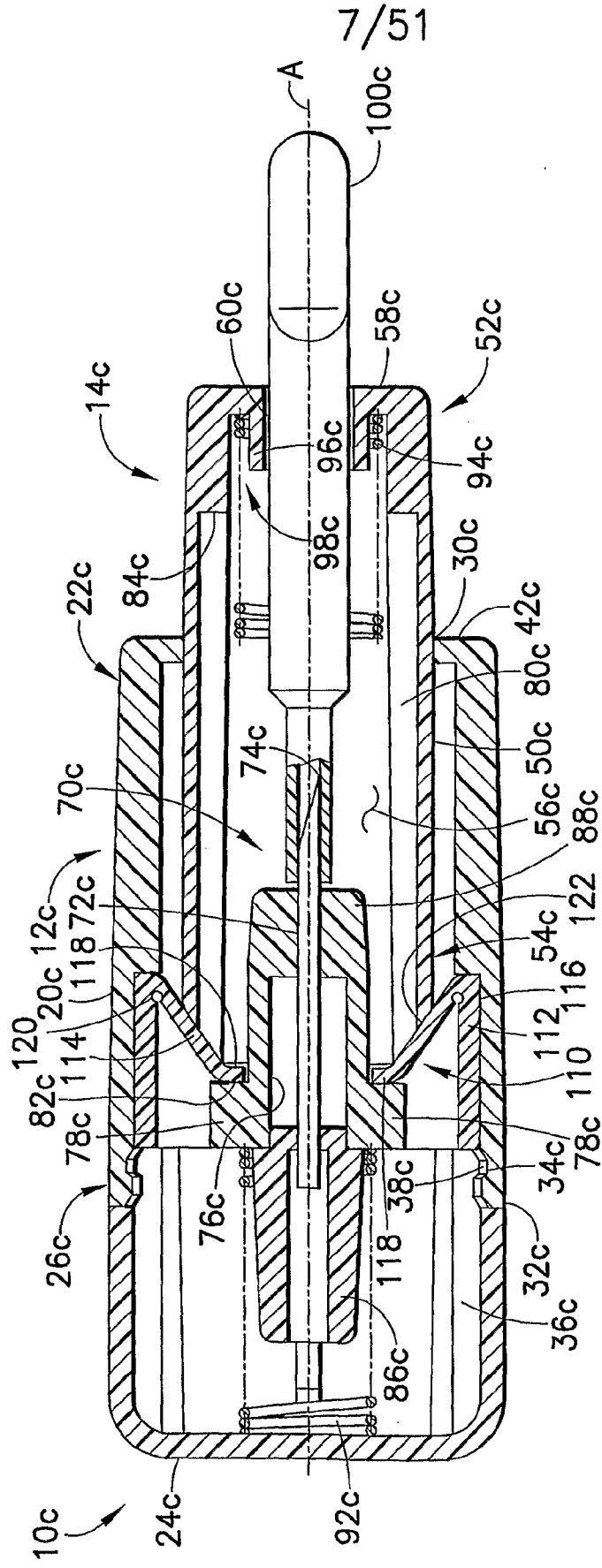


FIG.13



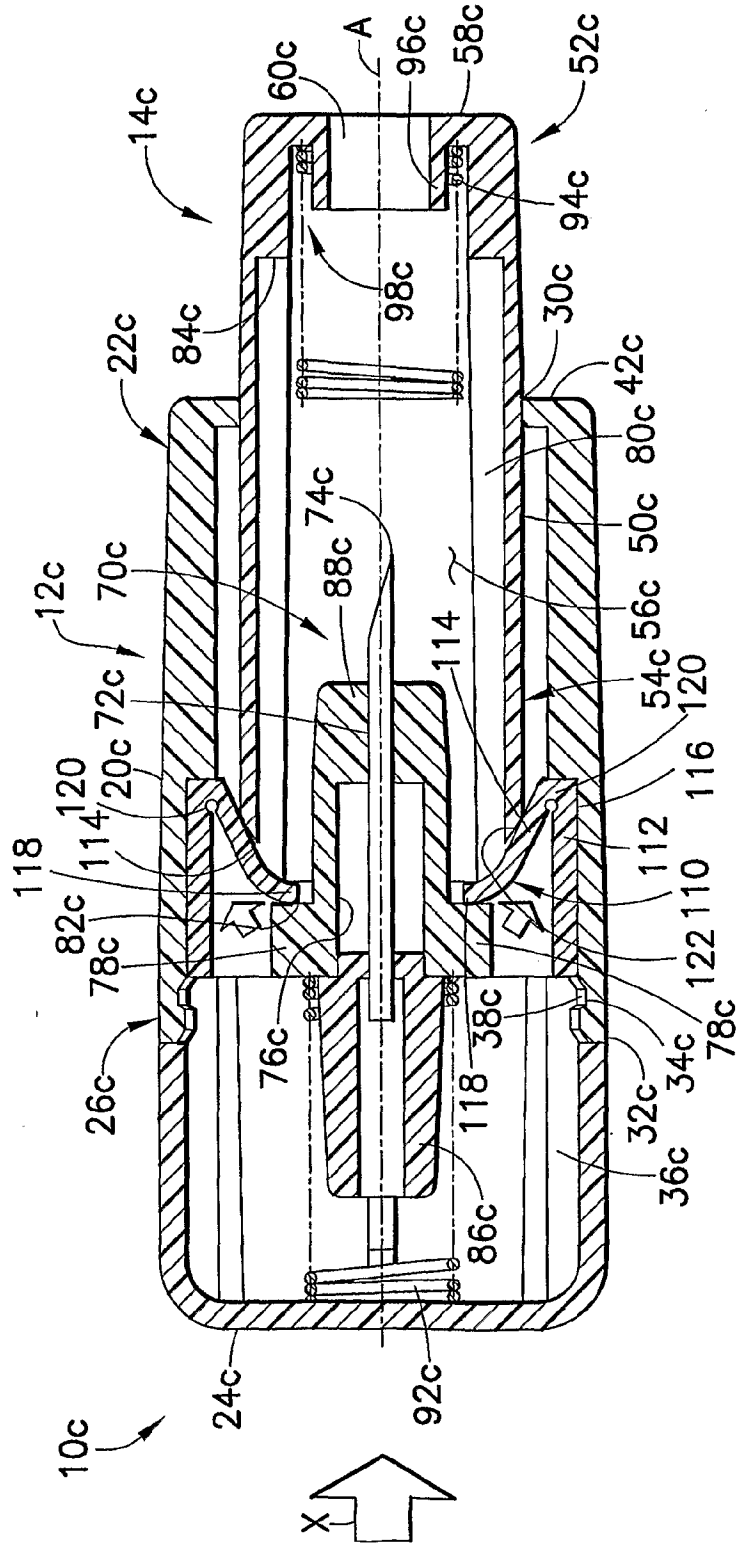


FIG.14

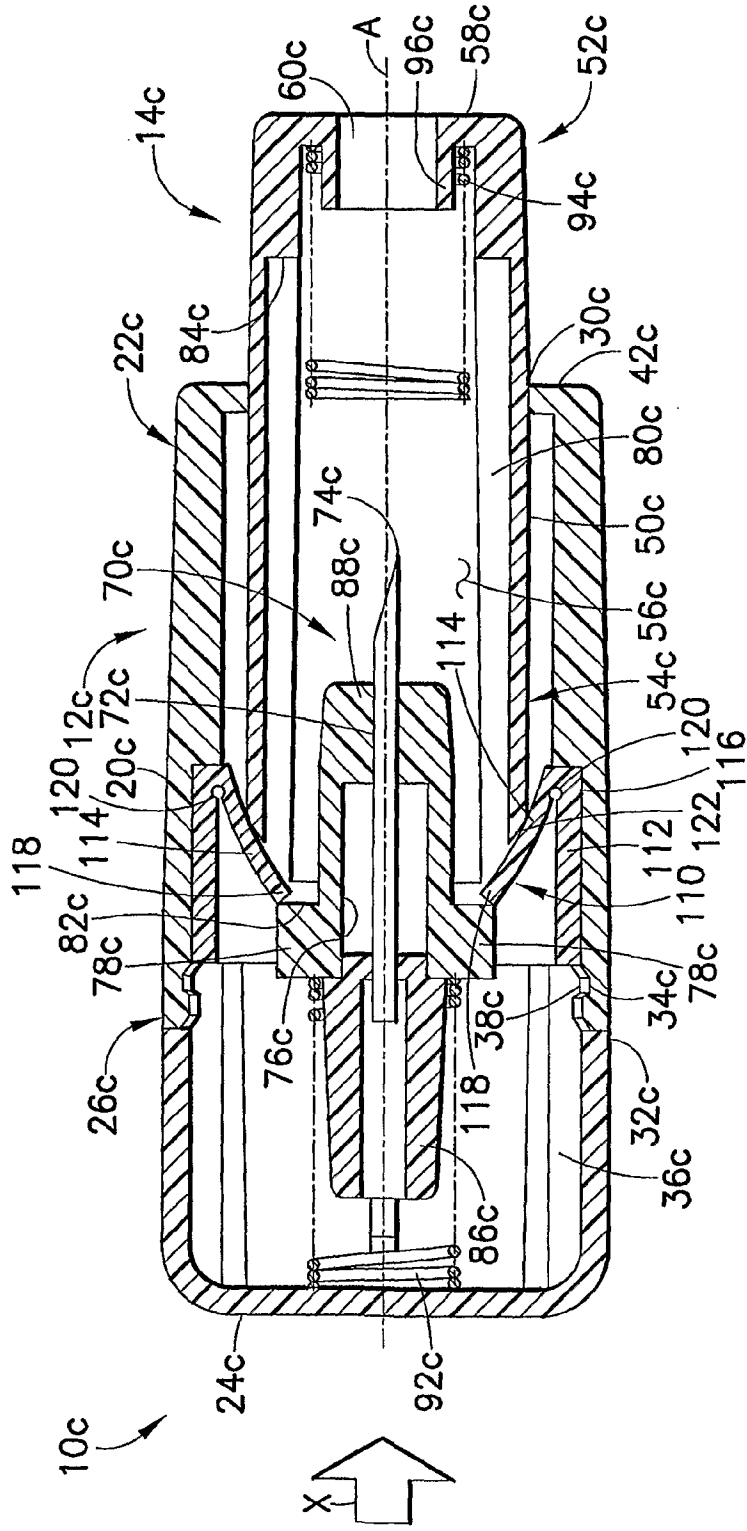


FIG.15

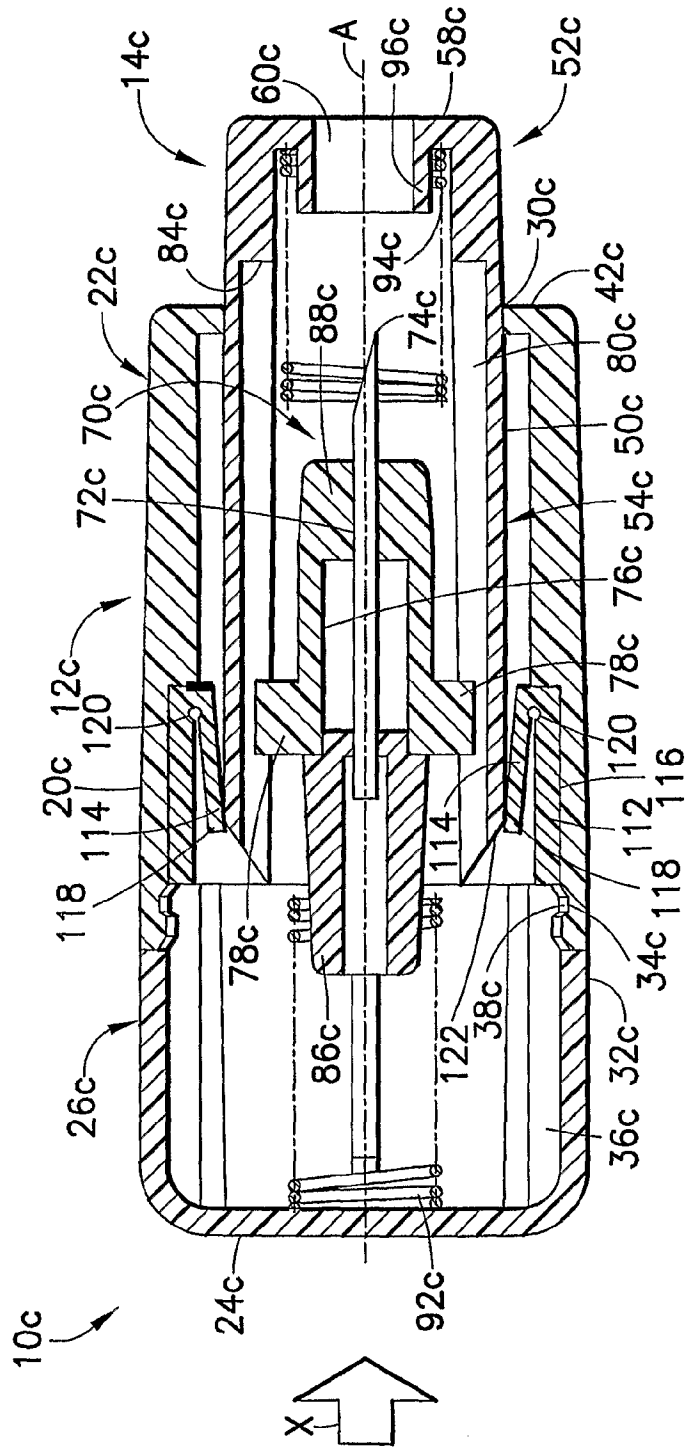


FIG.16

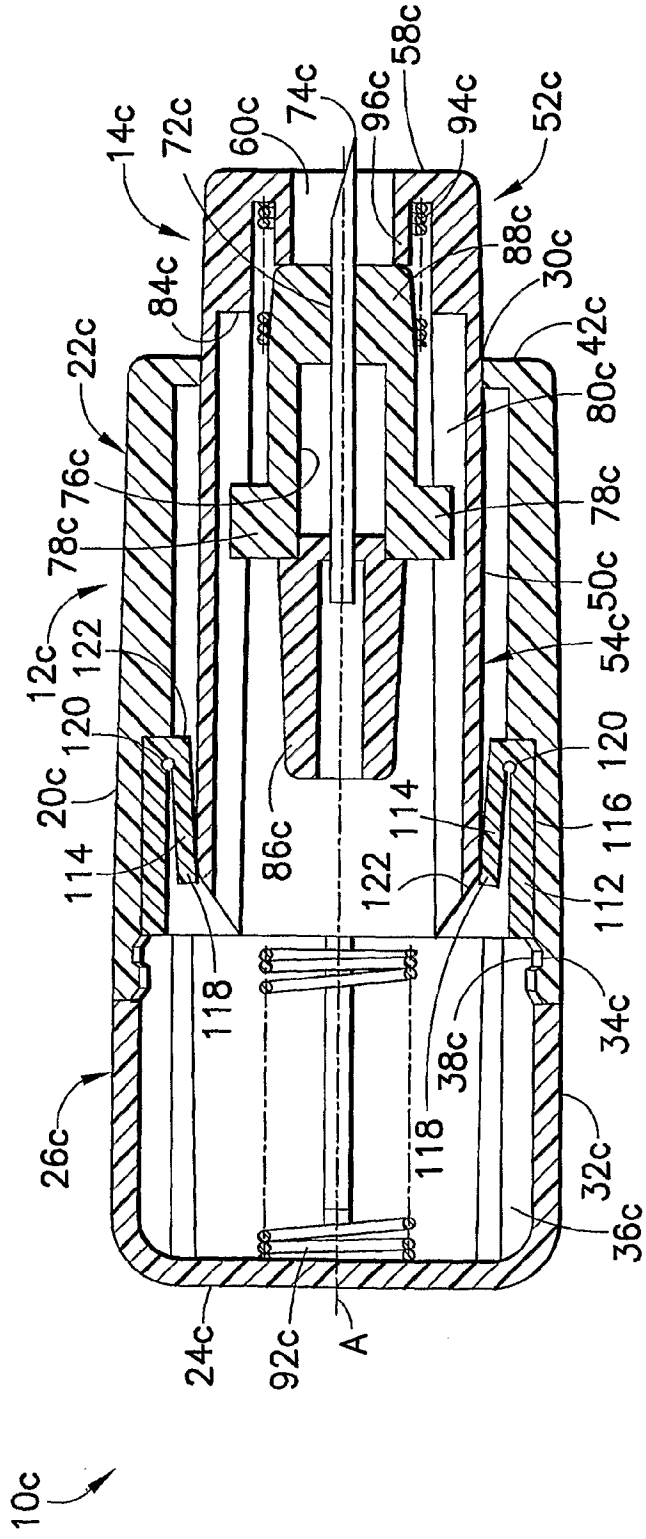


FIG.17

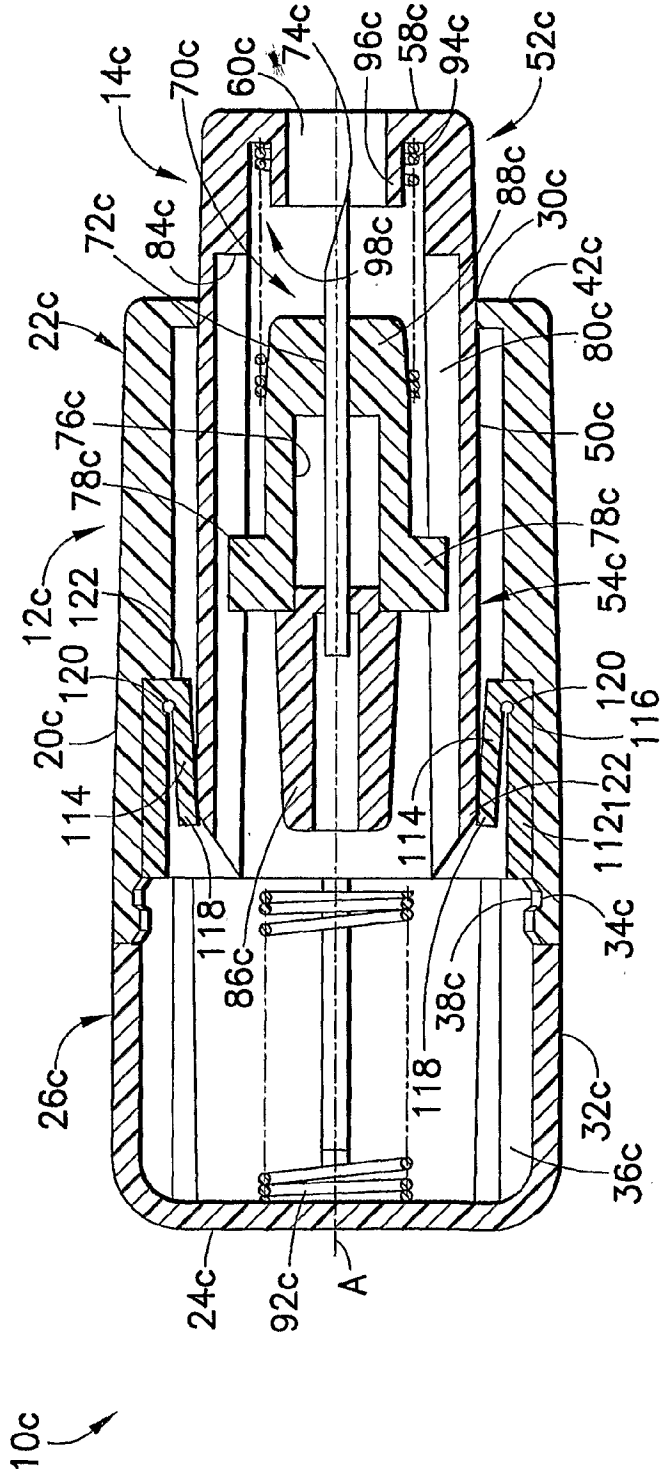


FIG.18

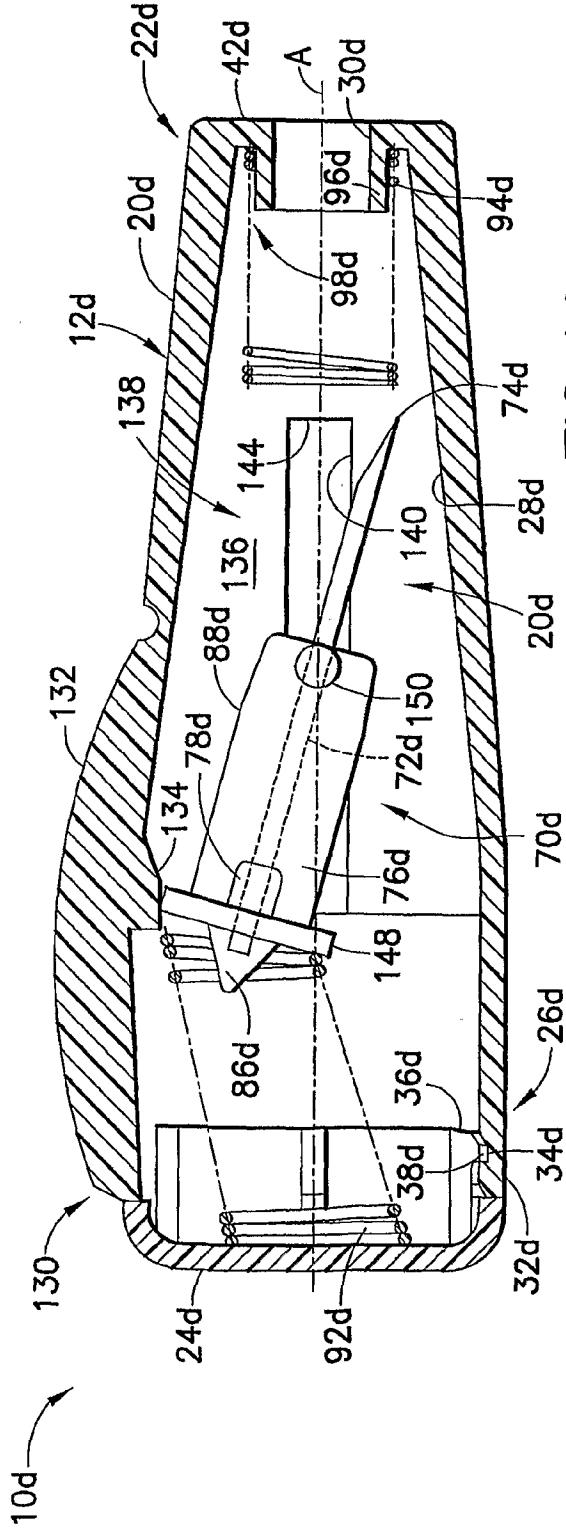


FIG. 19

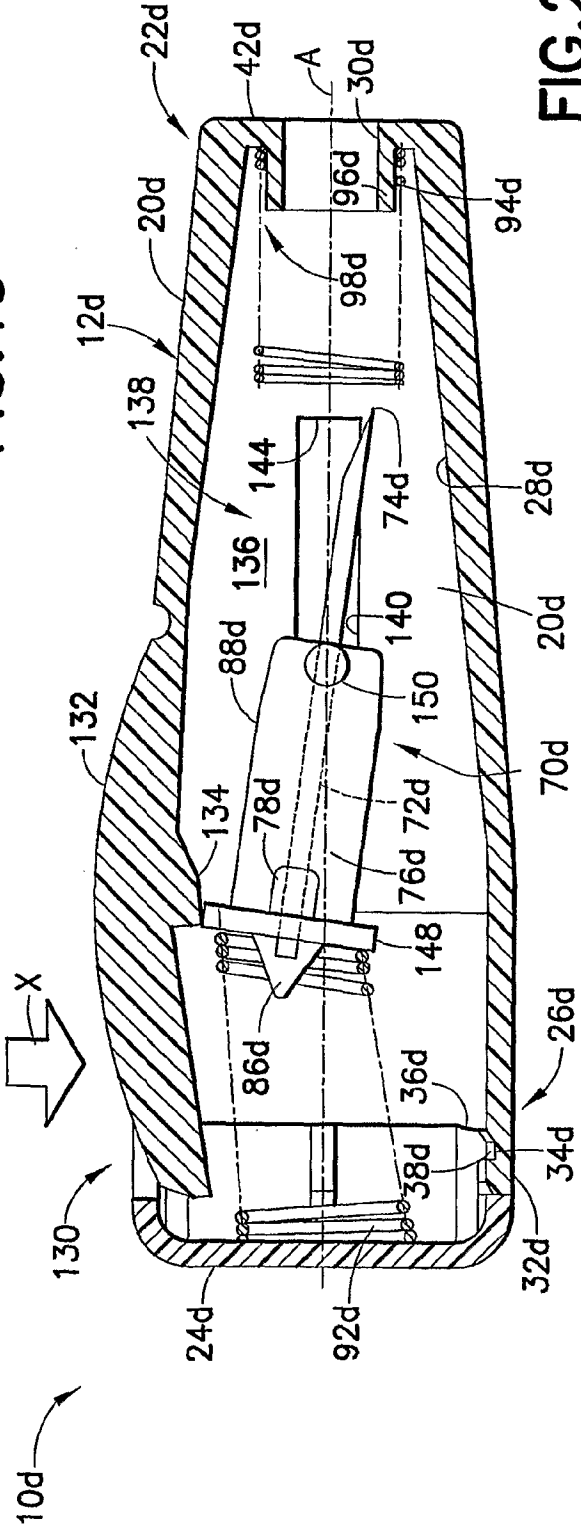


FIG. 20

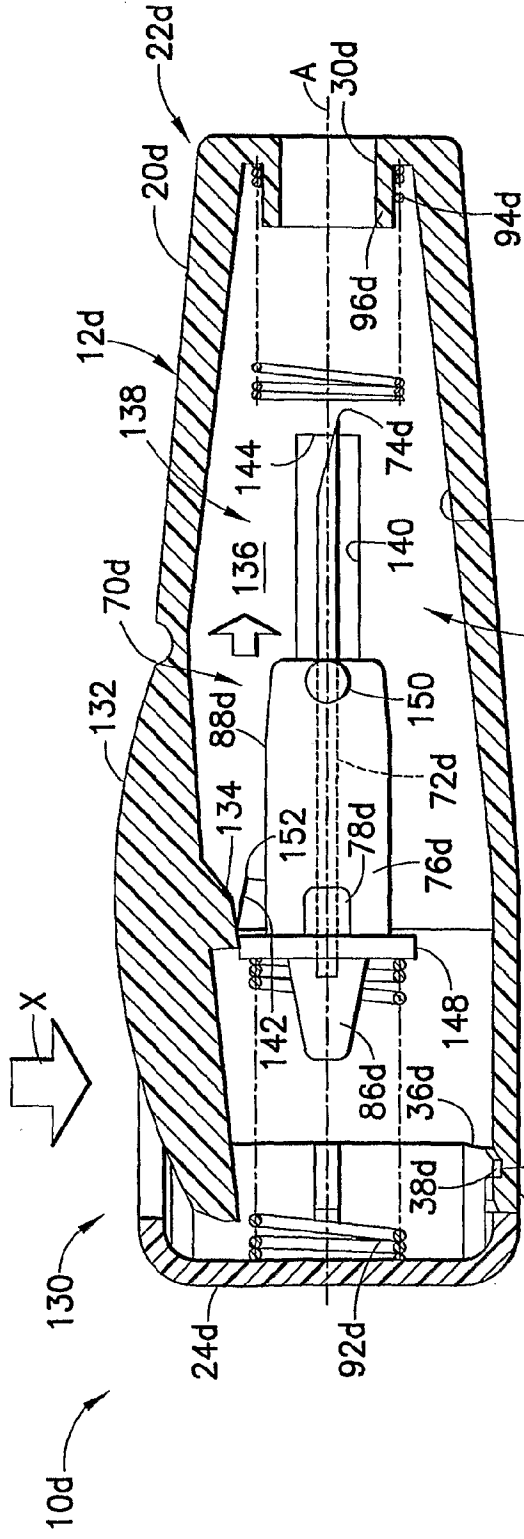


FIG. 21

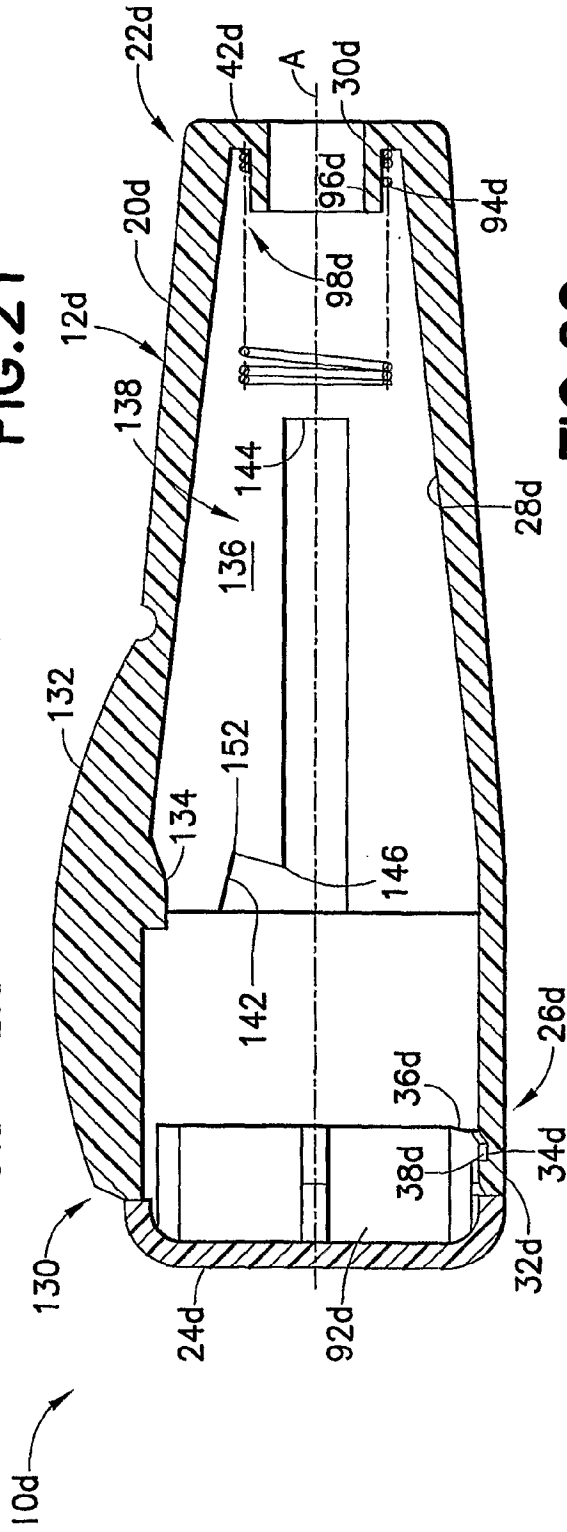


FIG. 22

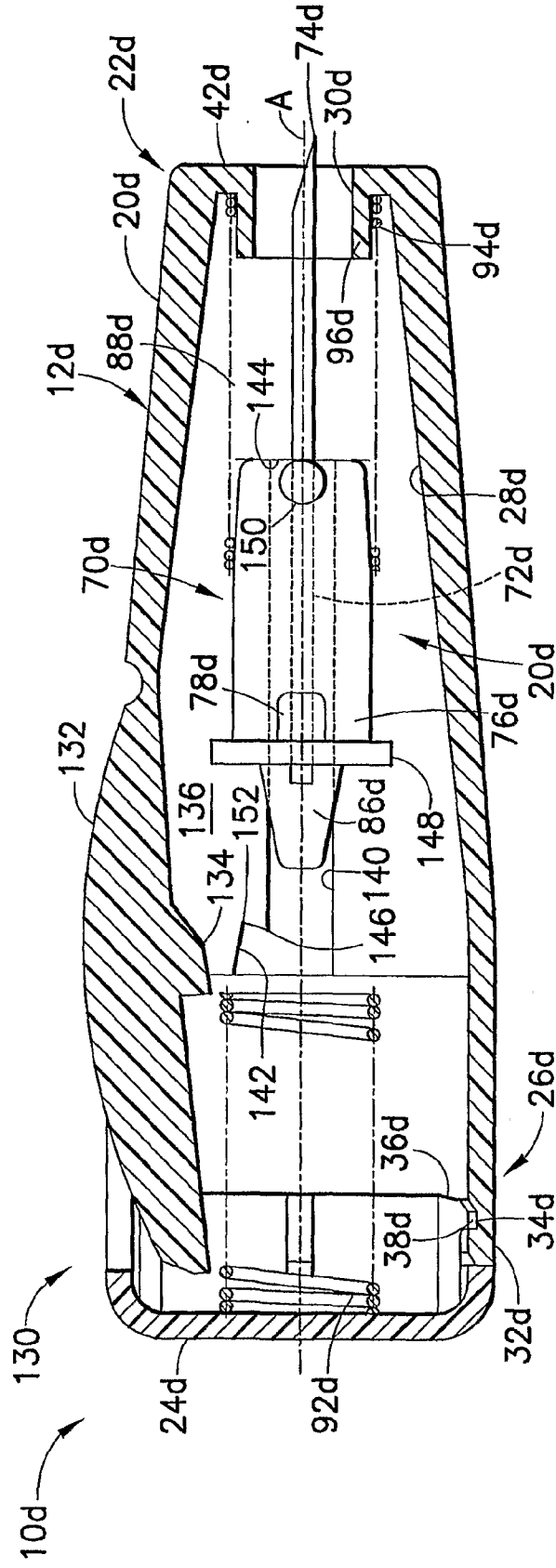


FIG. 23



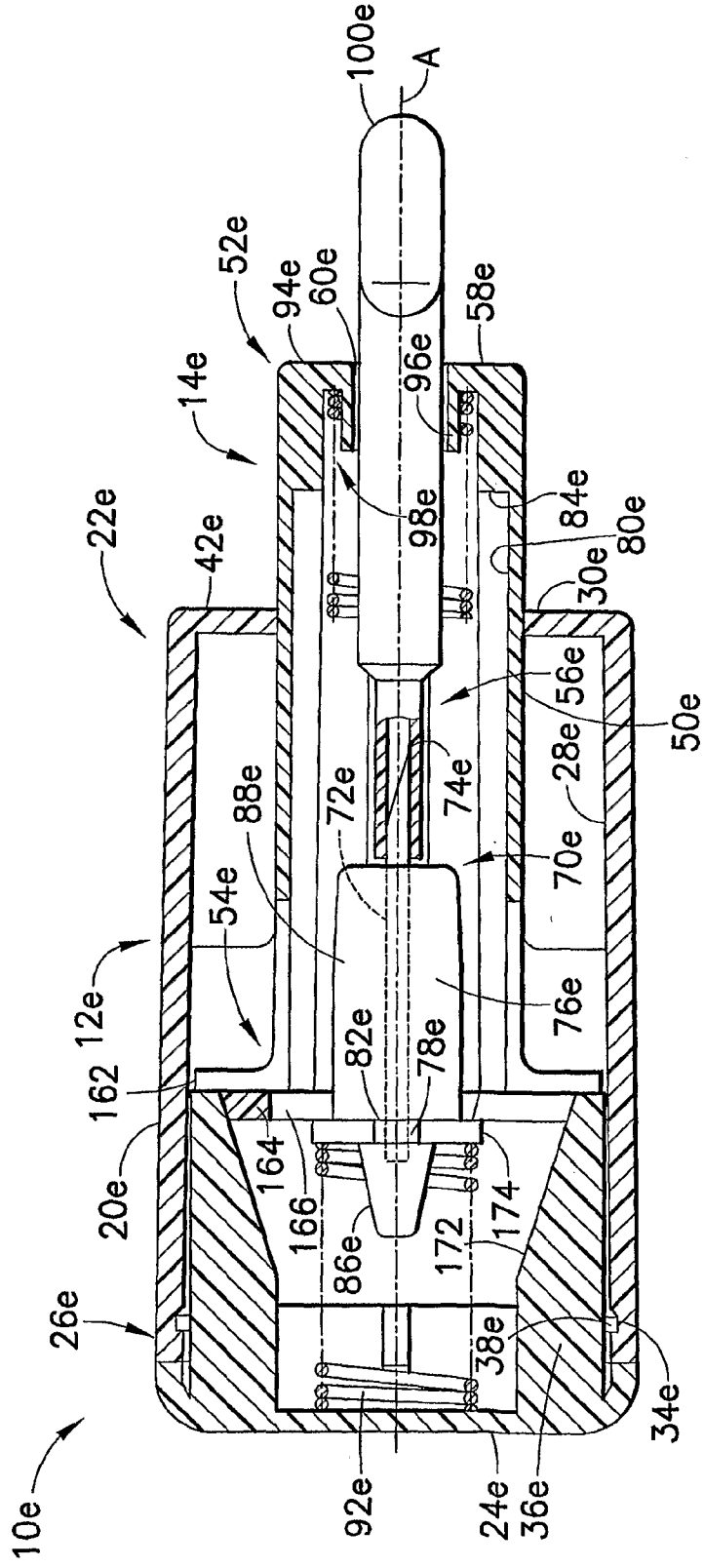


FIG.24

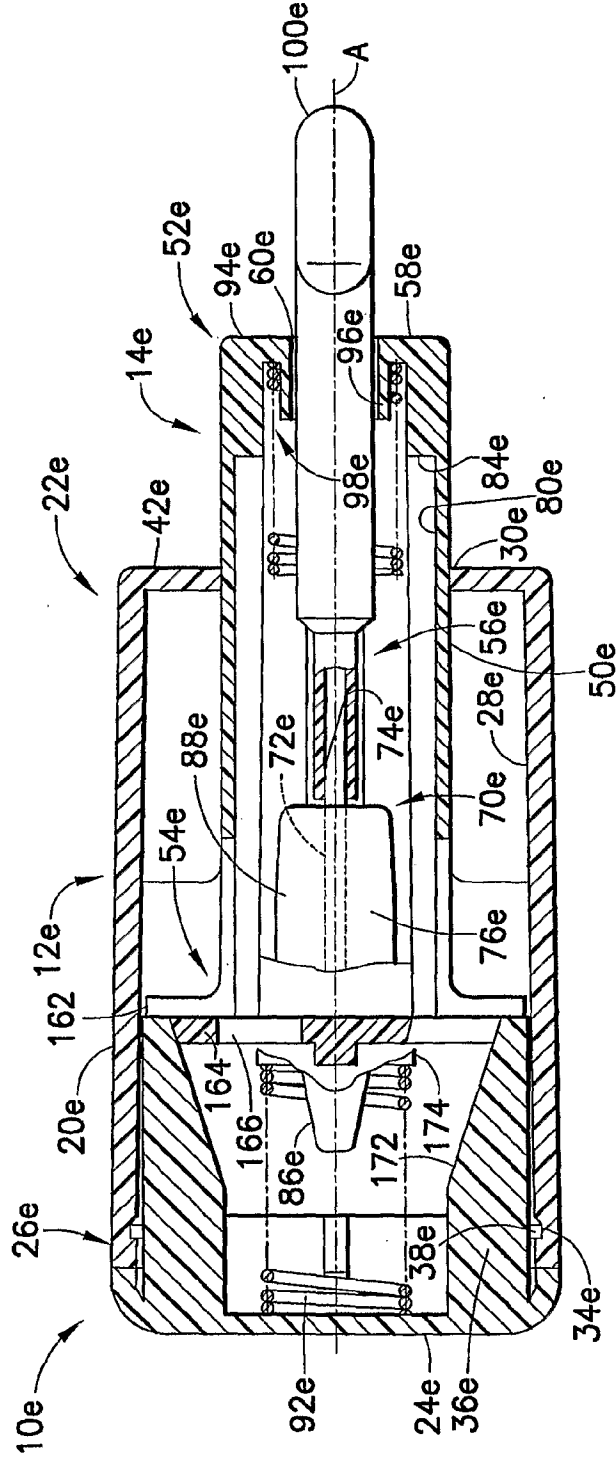


FIG. 25

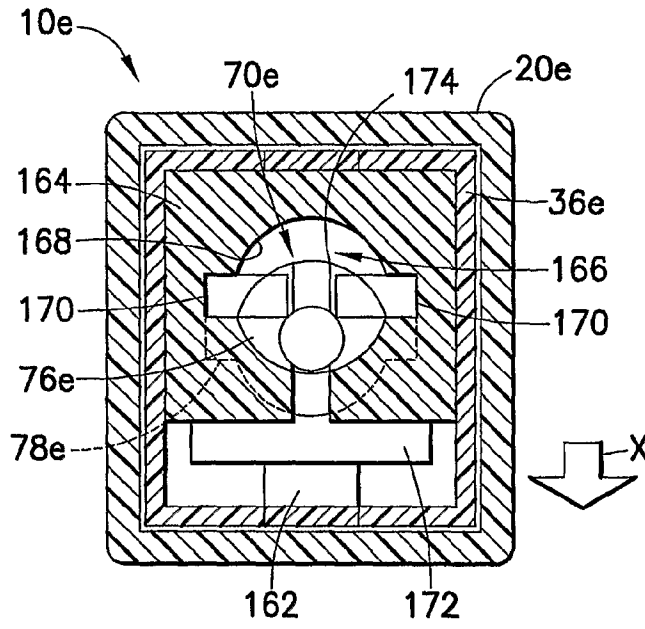


FIG. 26

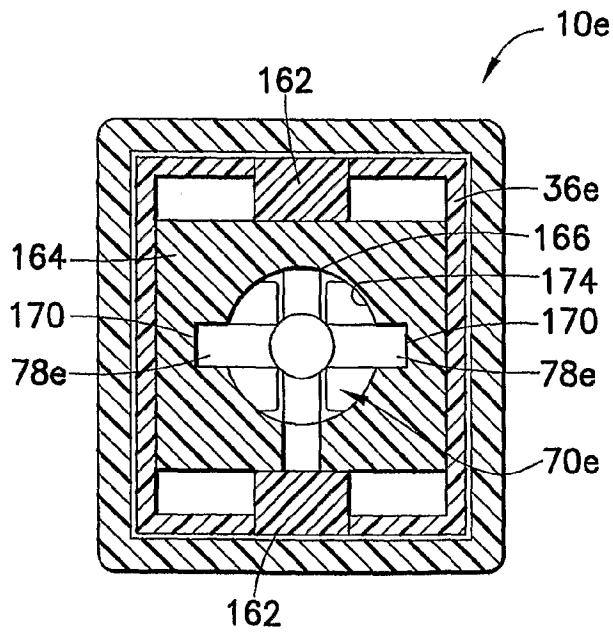


FIG. 27

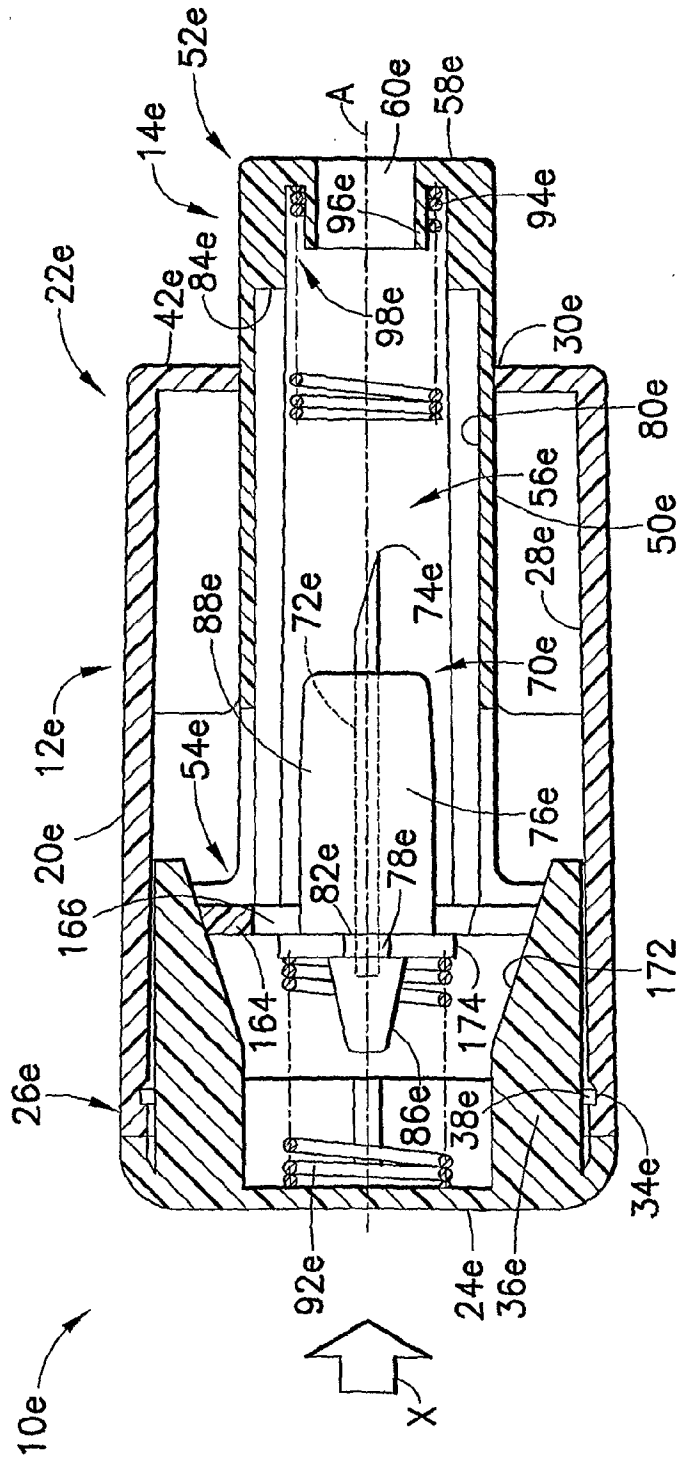


FIG.28

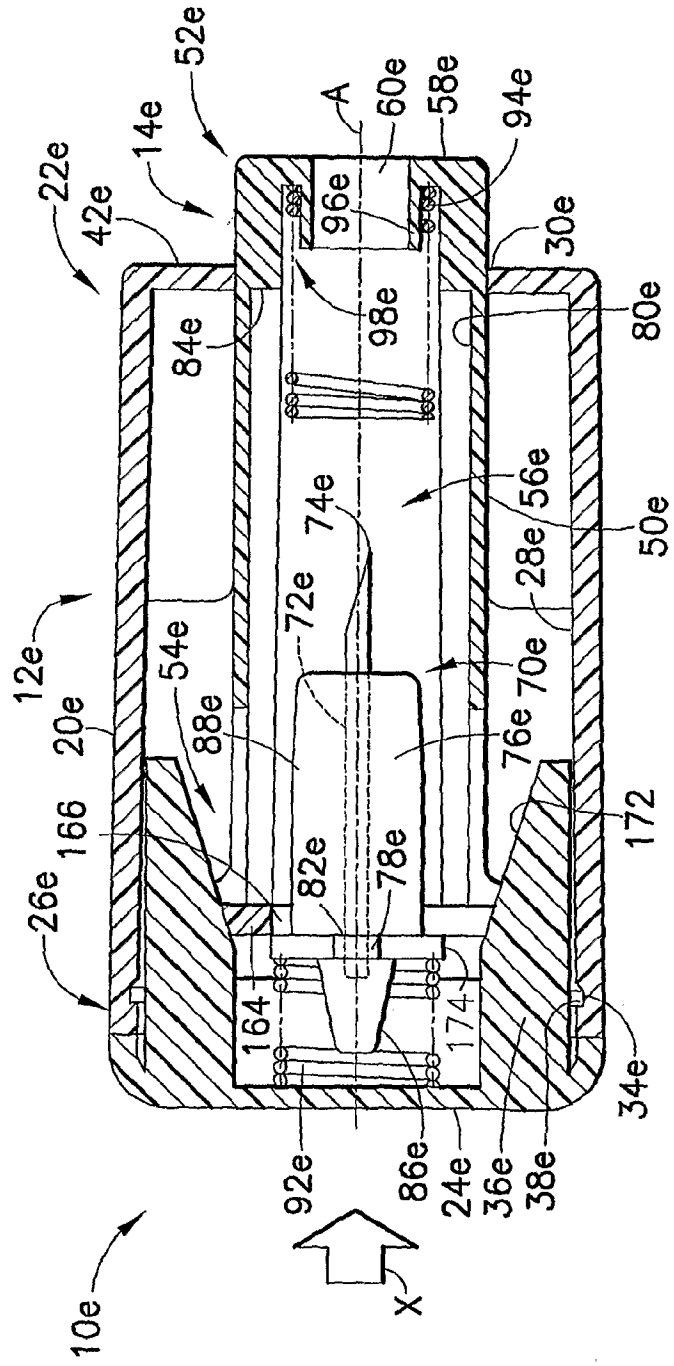


FIG.29

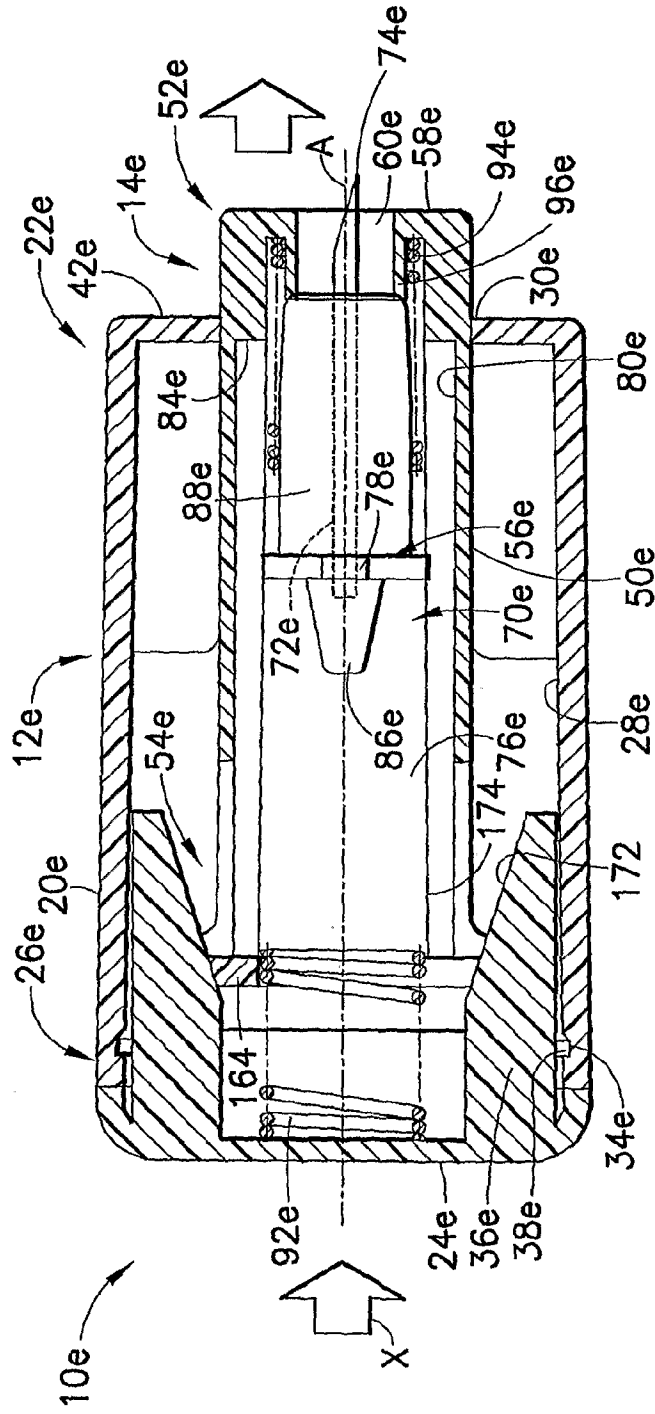


FIG.30

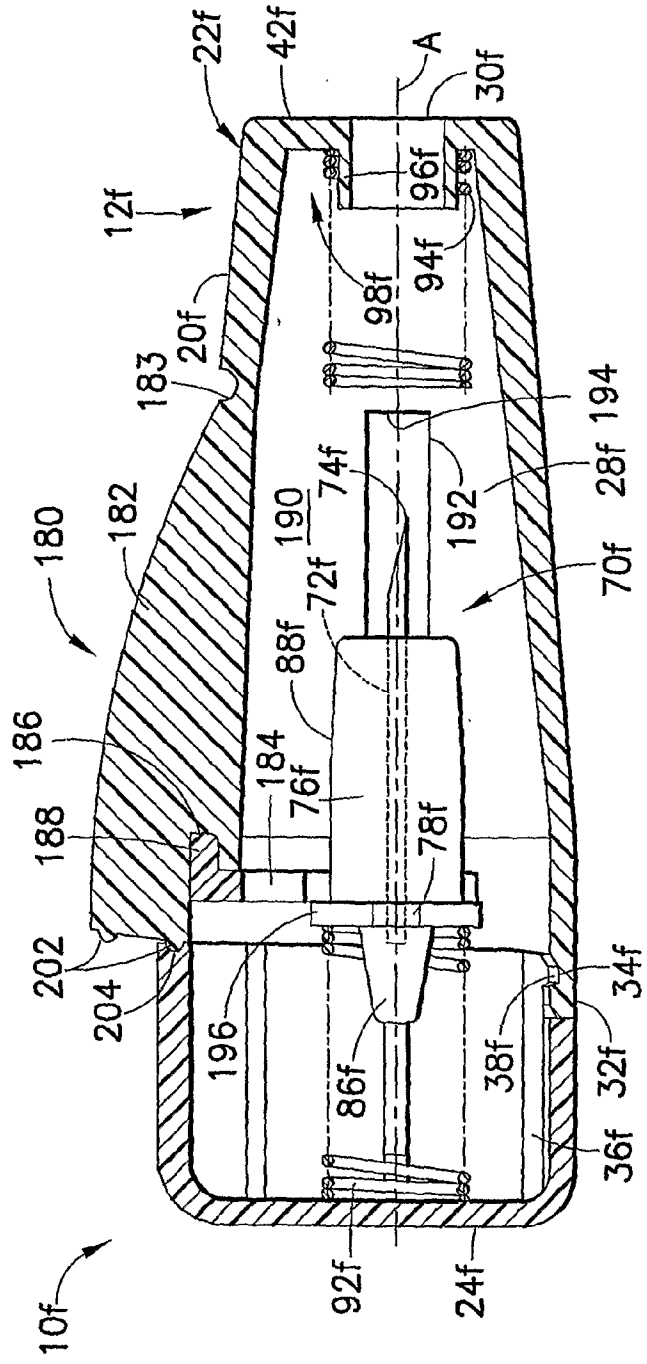


FIG.31

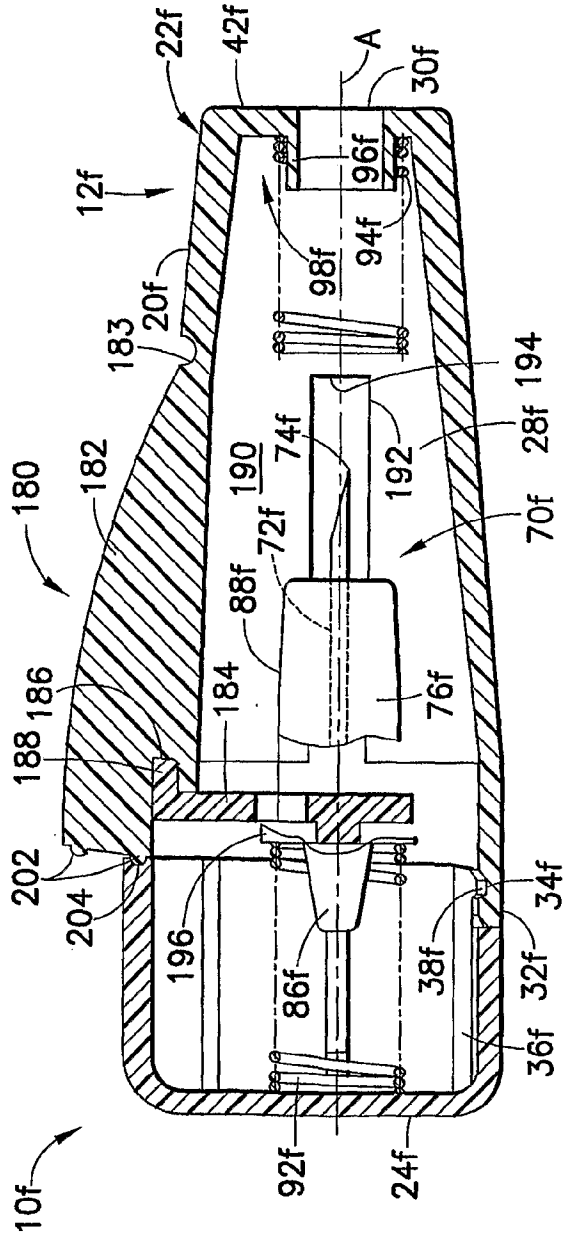


FIG.32



24/51

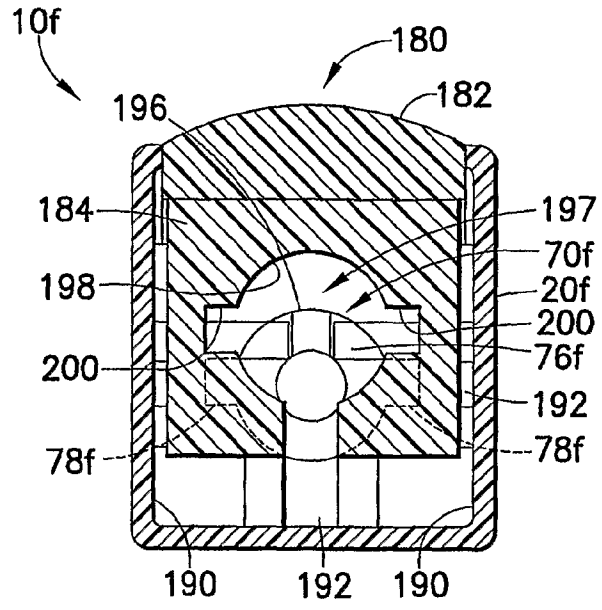


FIG.33

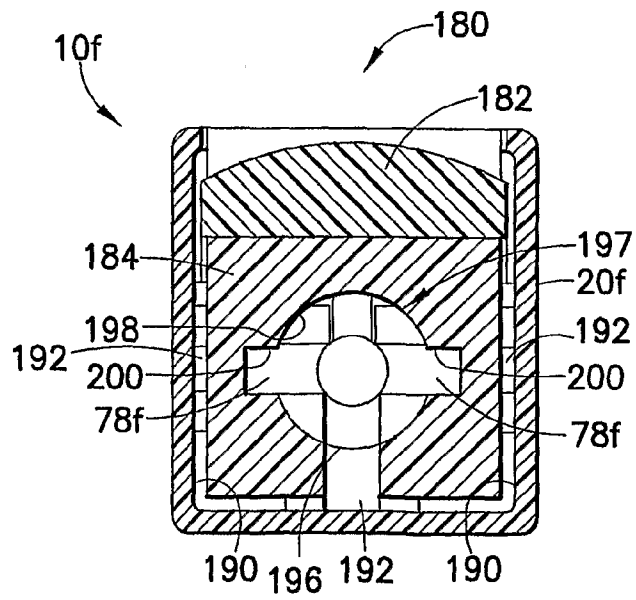


FIG.34

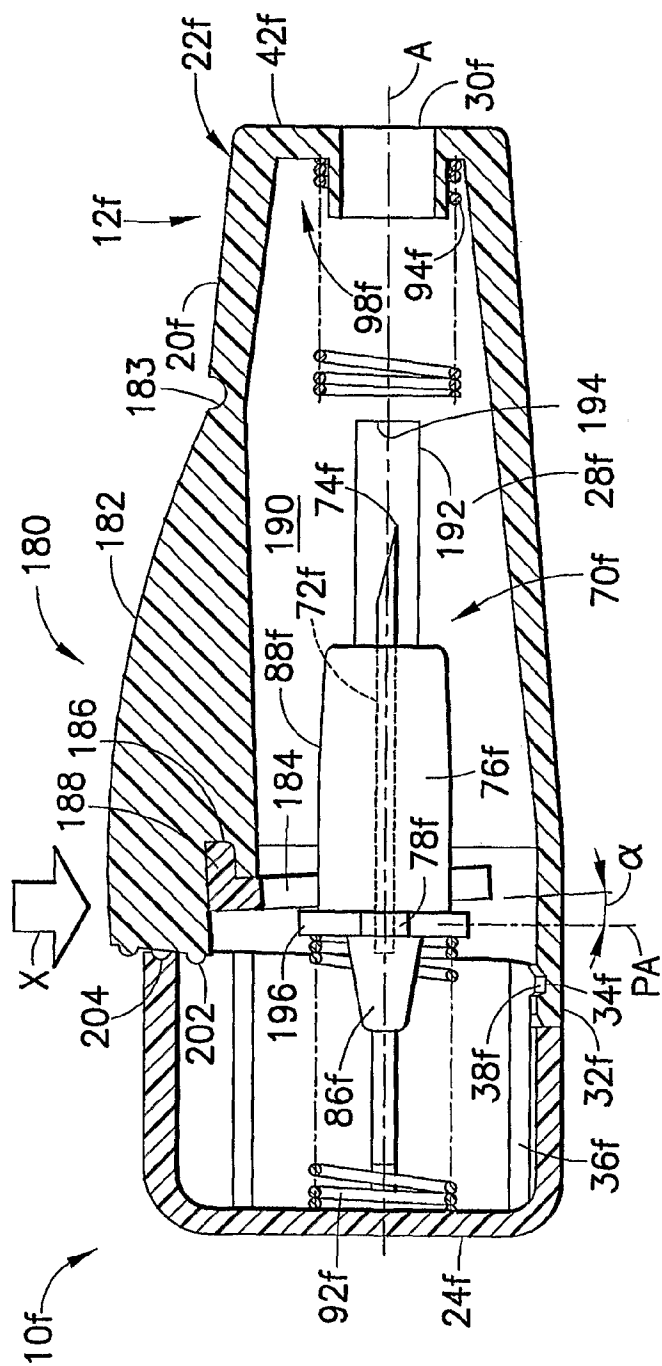


FIG. 35

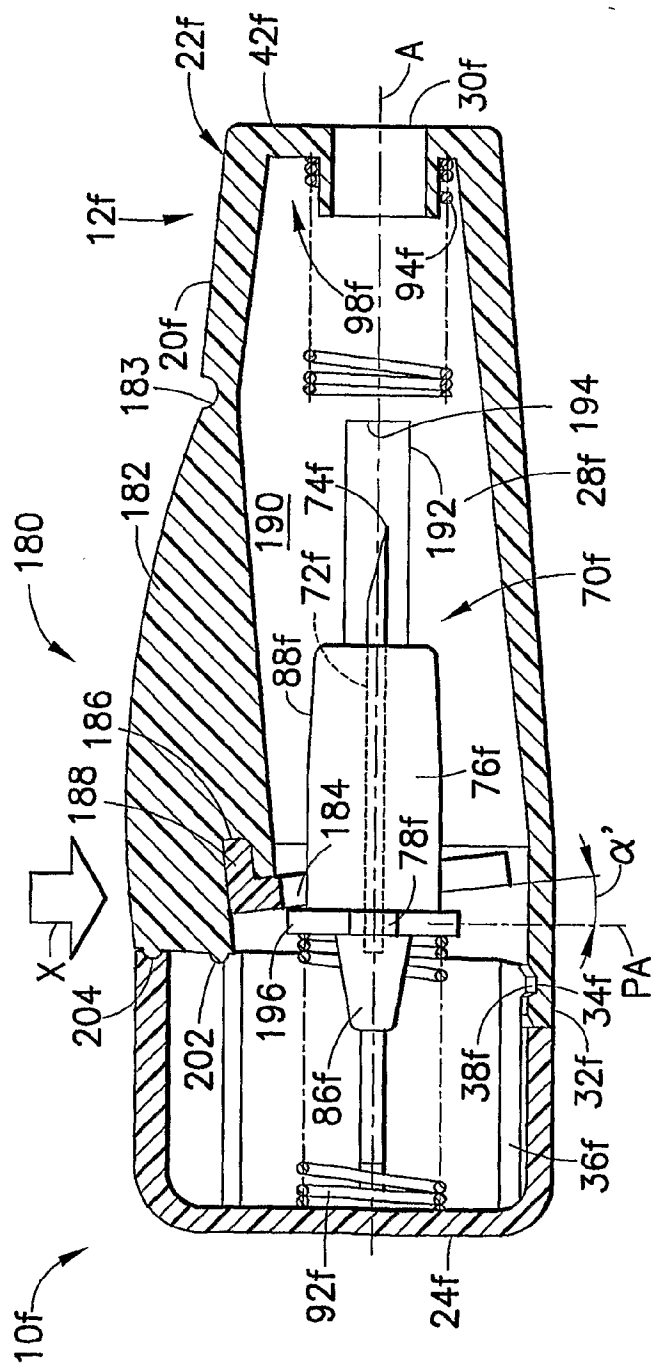


FIG.36

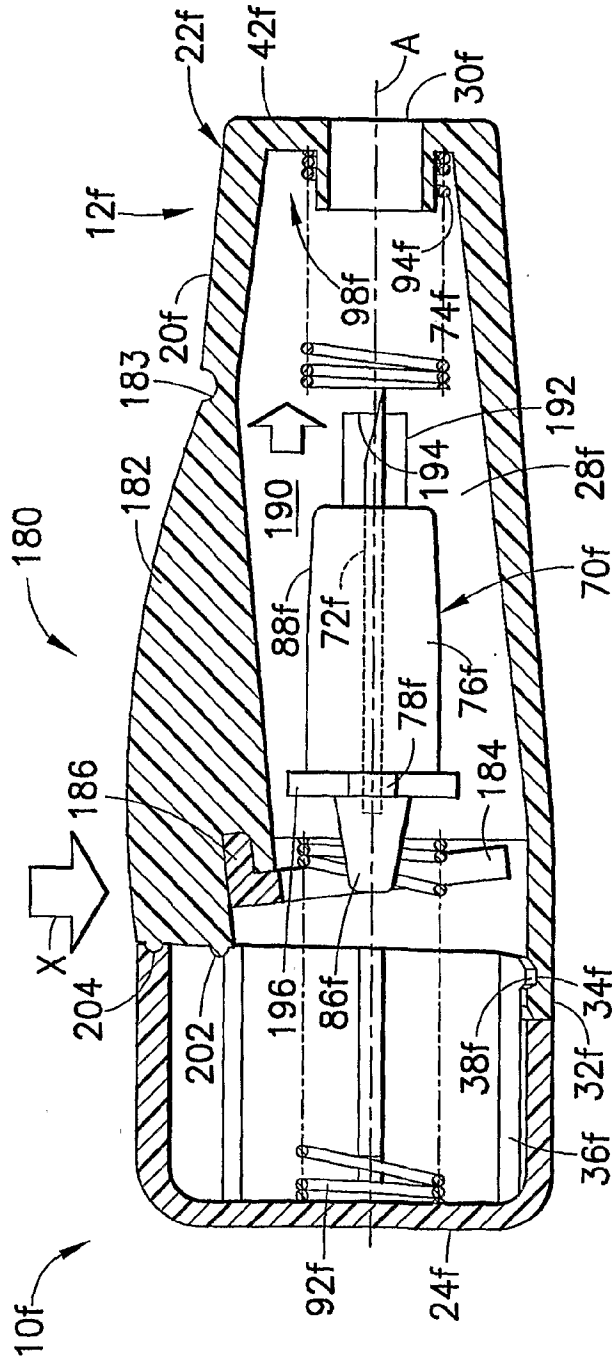


FIG.37

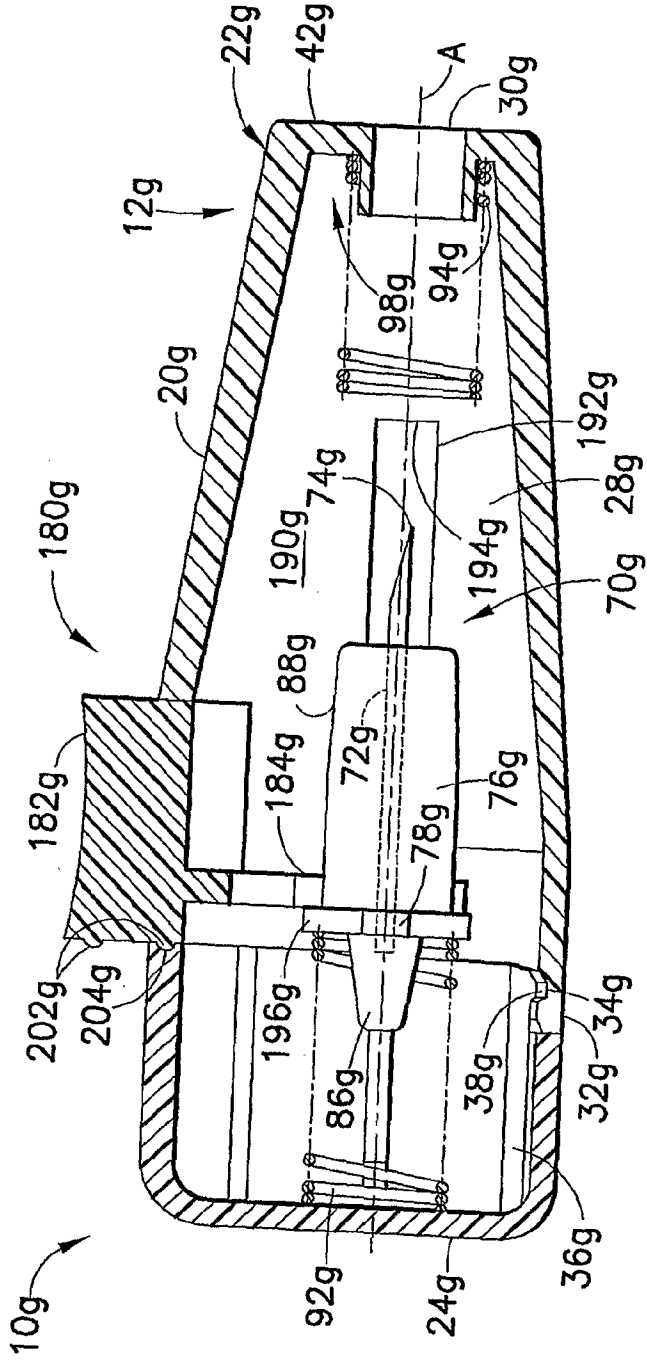


FIG.38

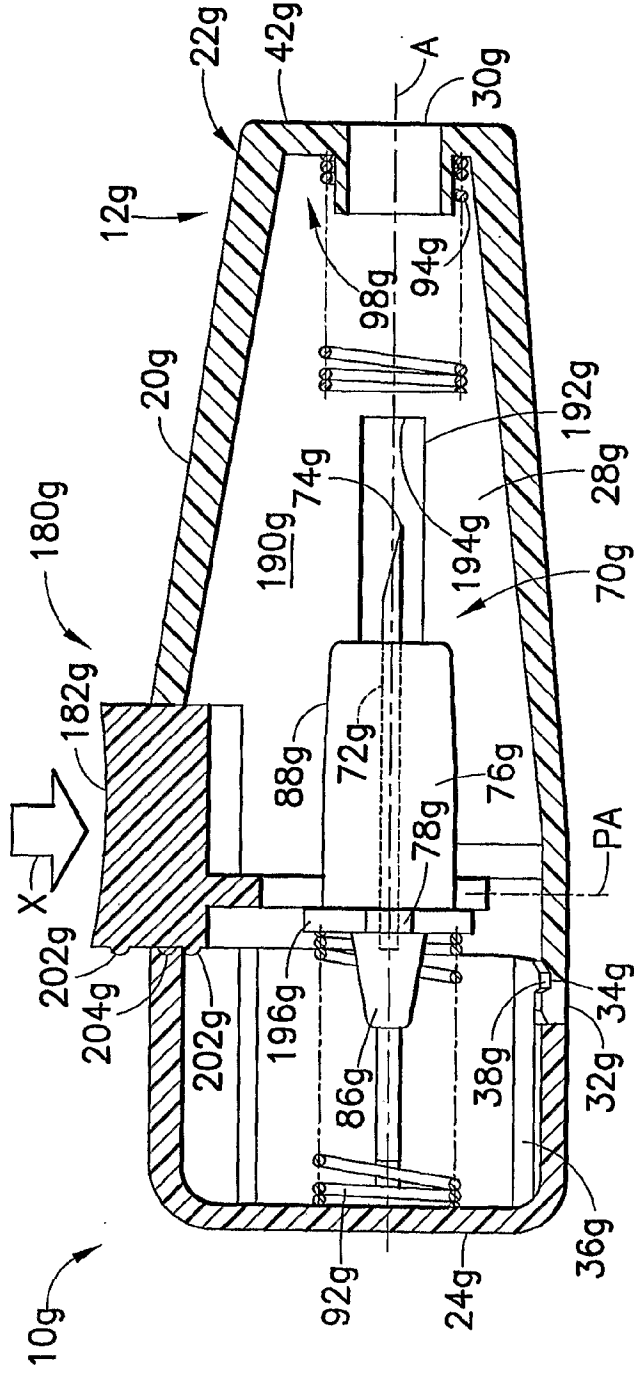


FIG.39

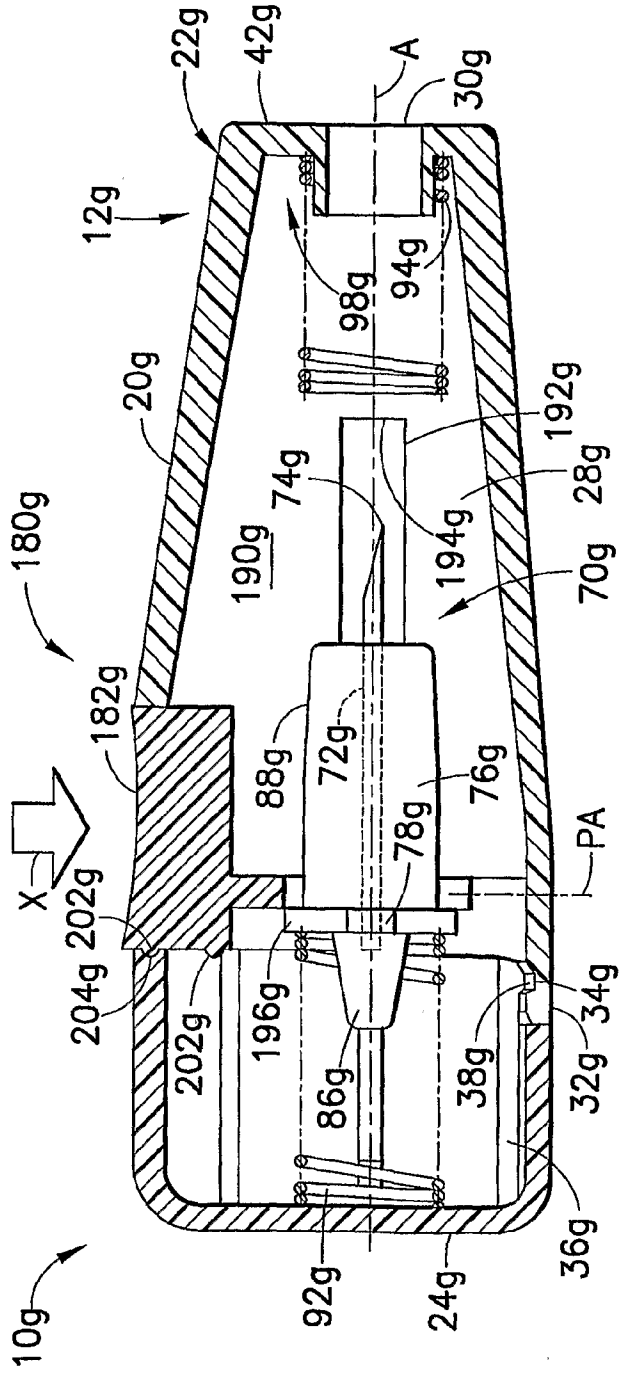


FIG. 40

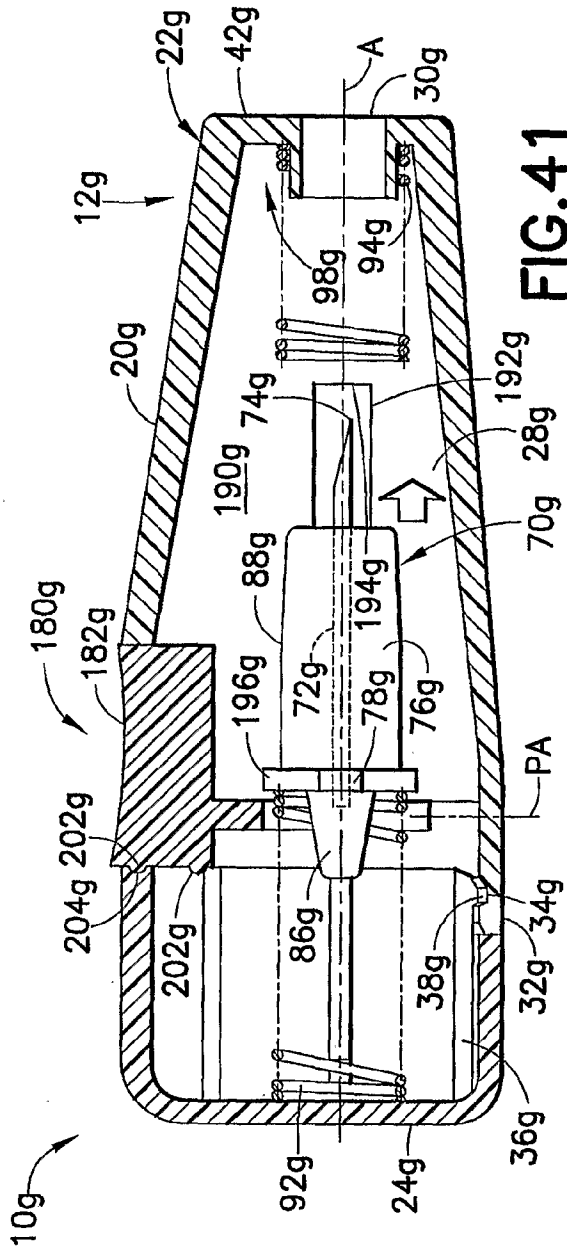


FIG. 41

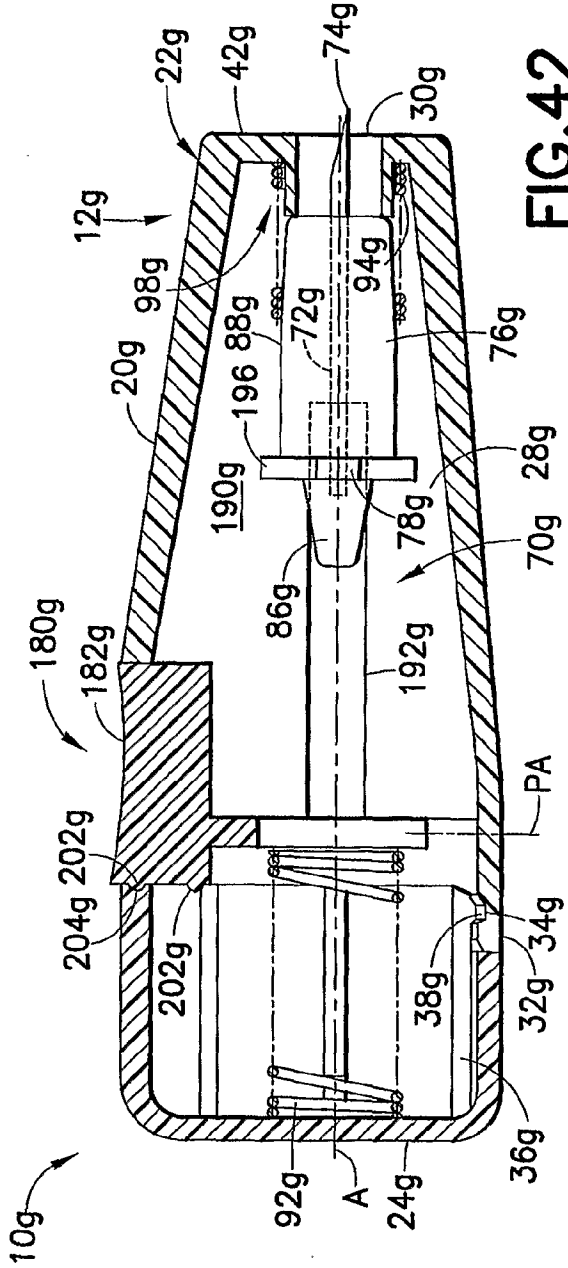


FIG. 42



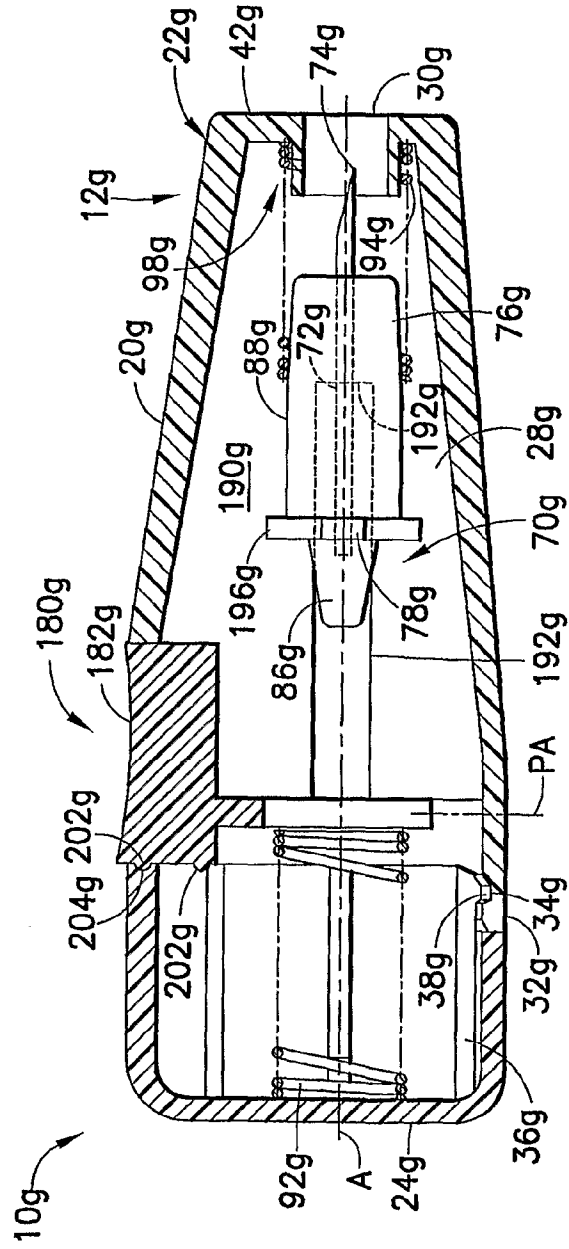
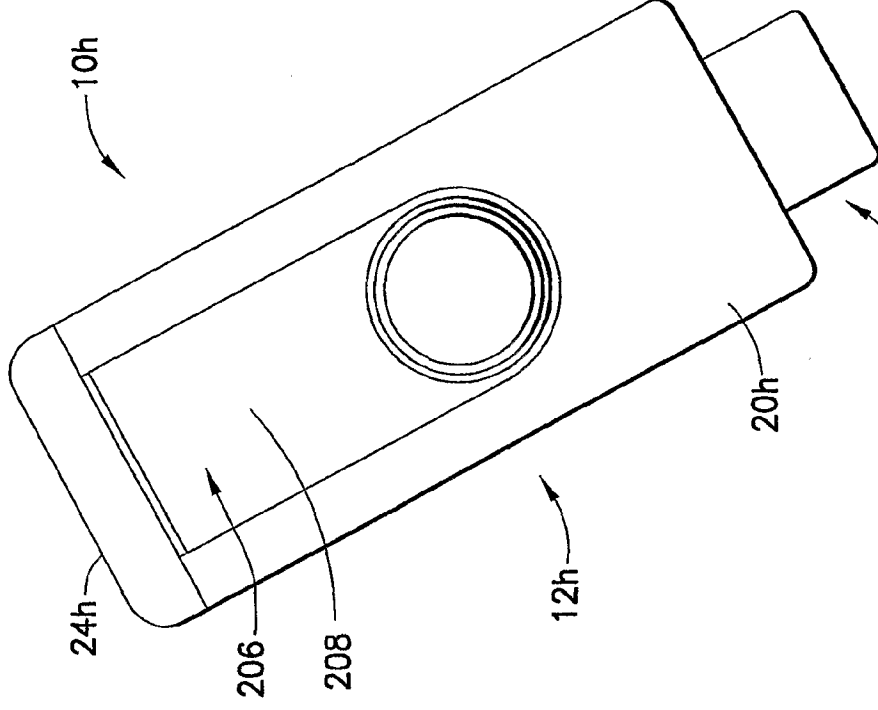
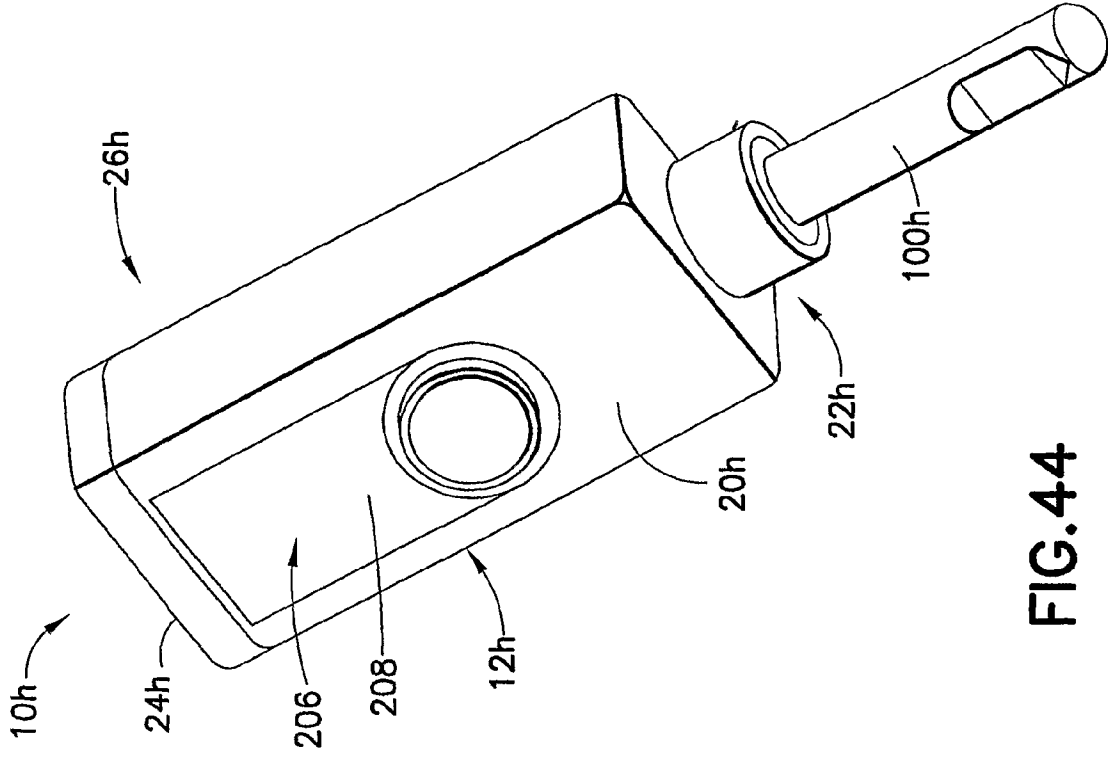
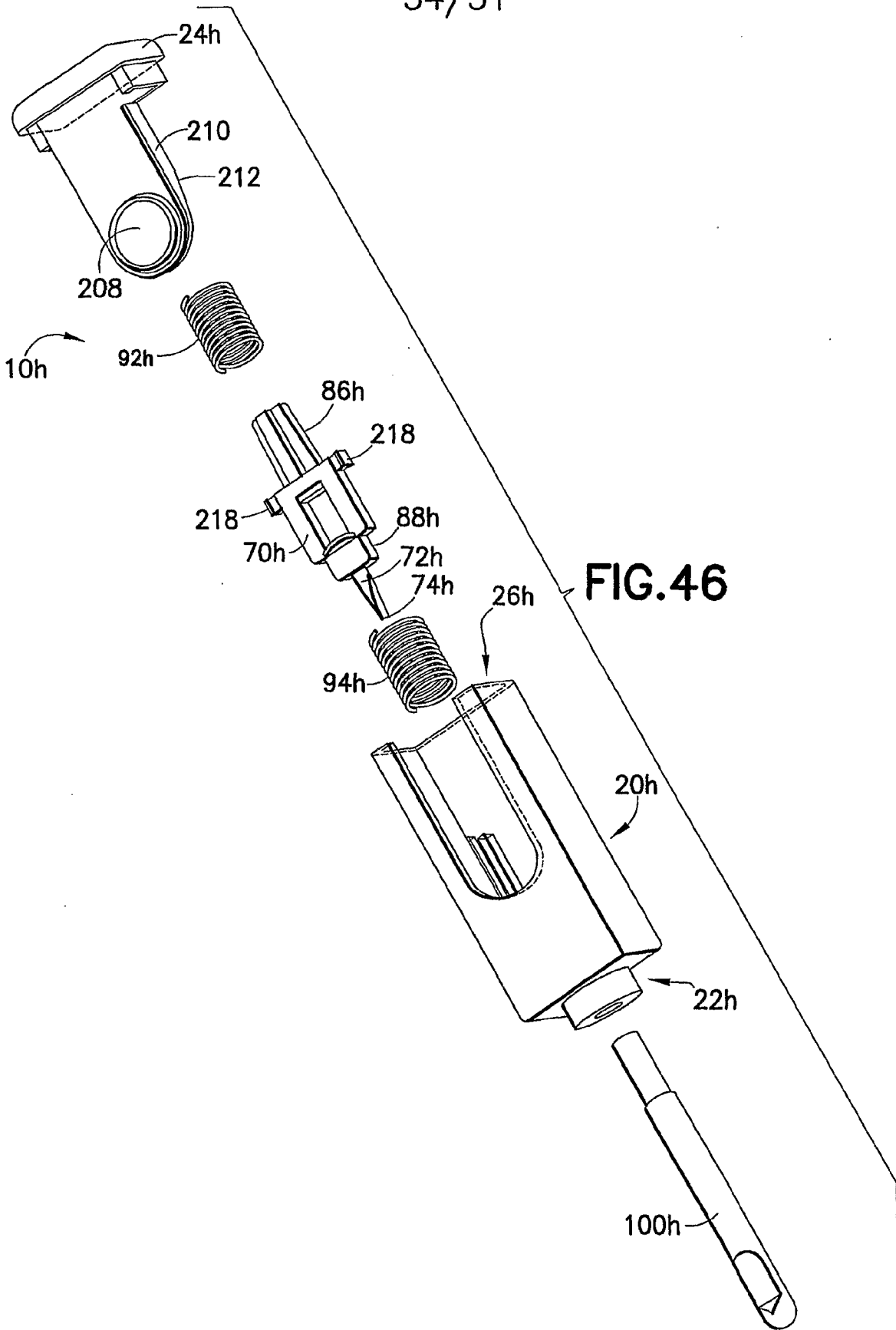


FIG.43





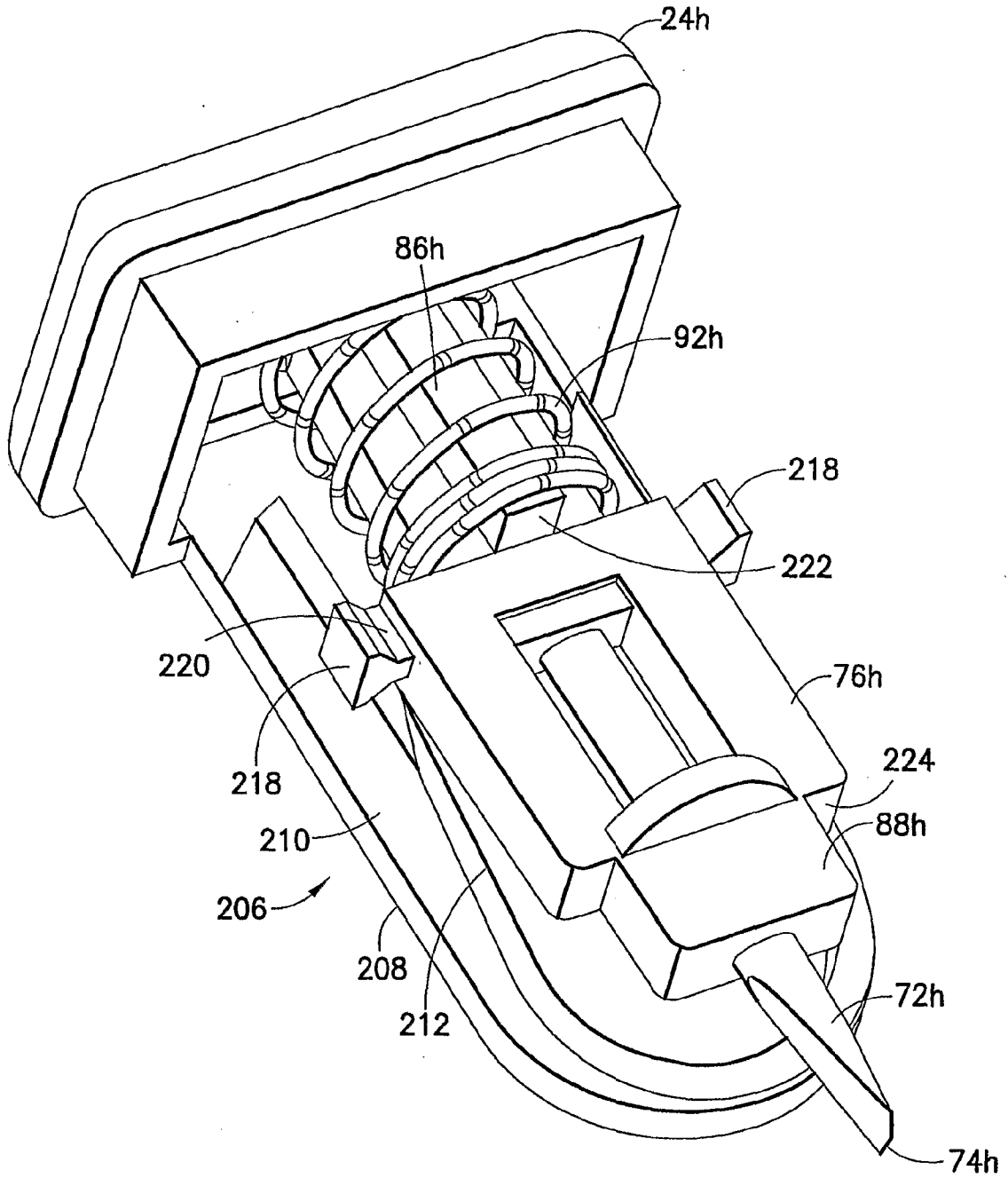


FIG.47

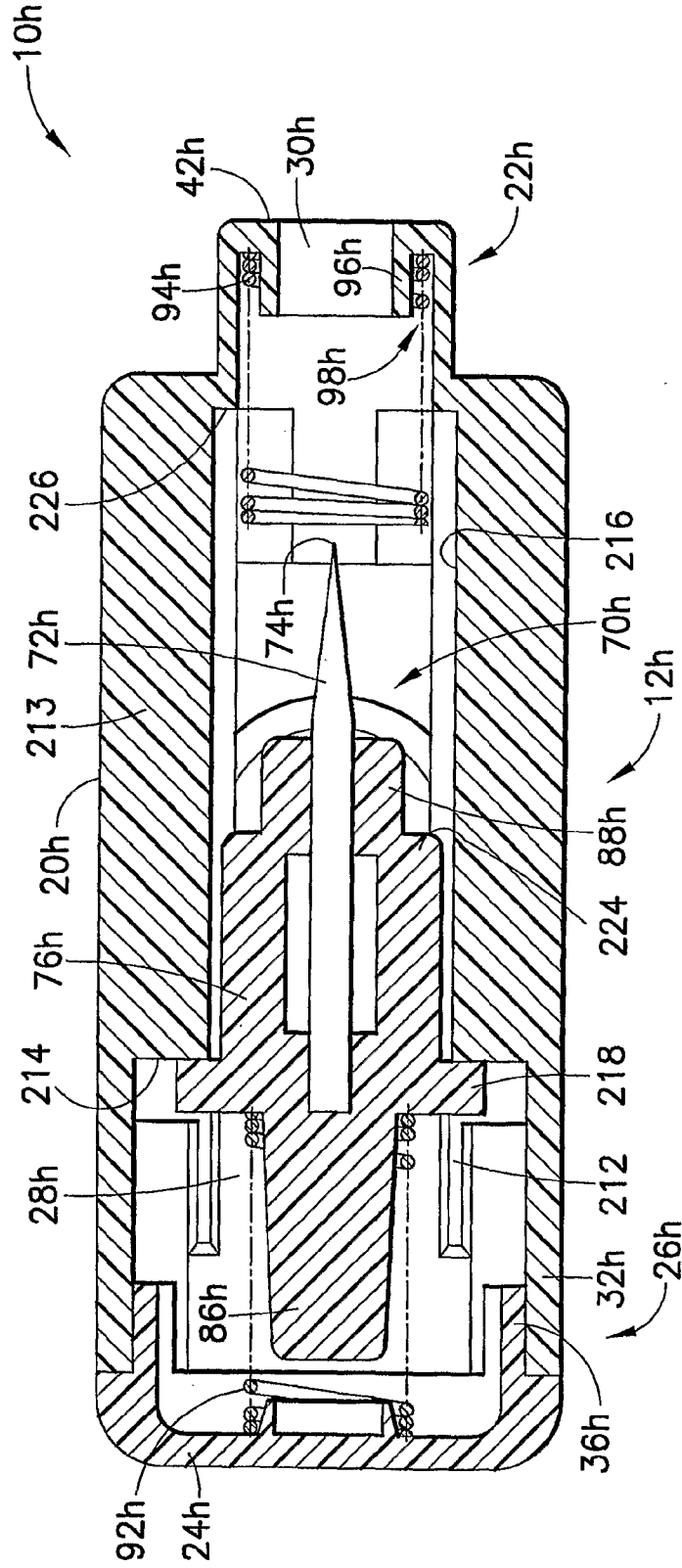


FIG.48

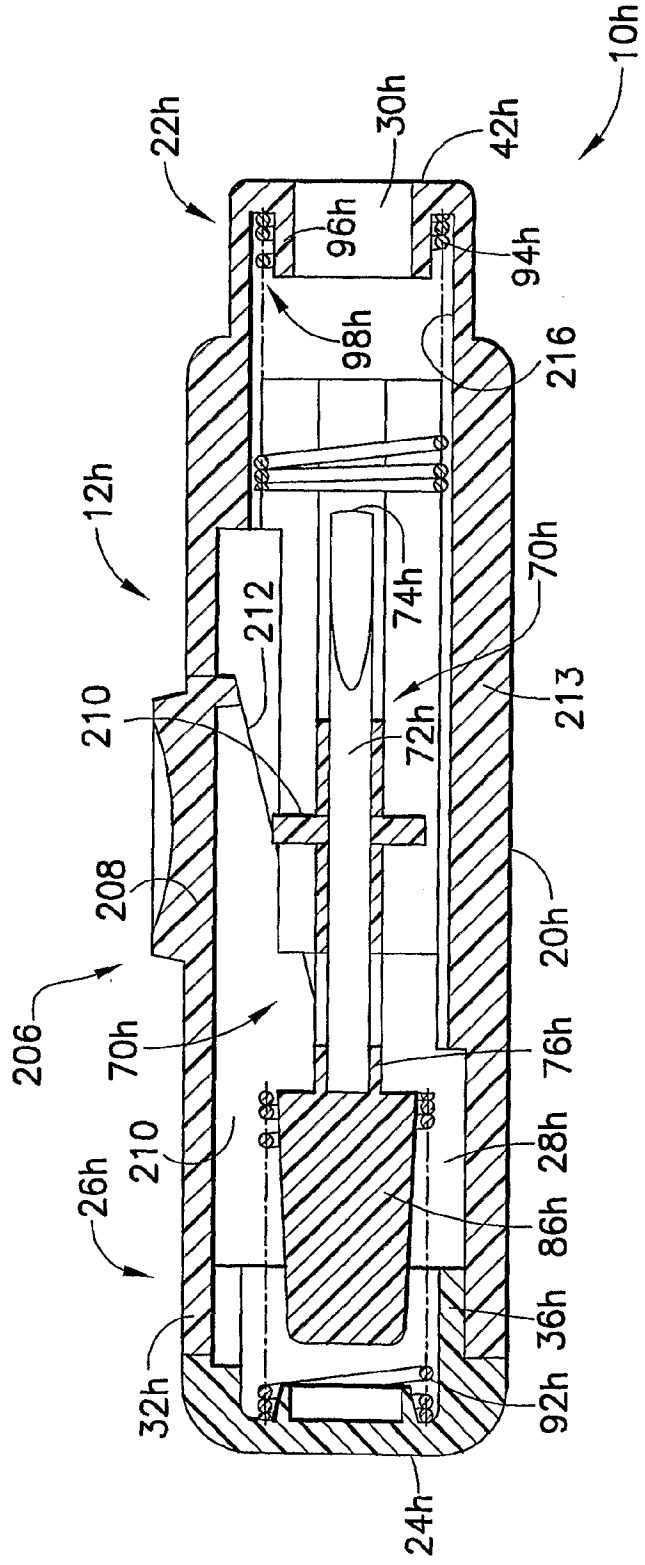


FIG.49

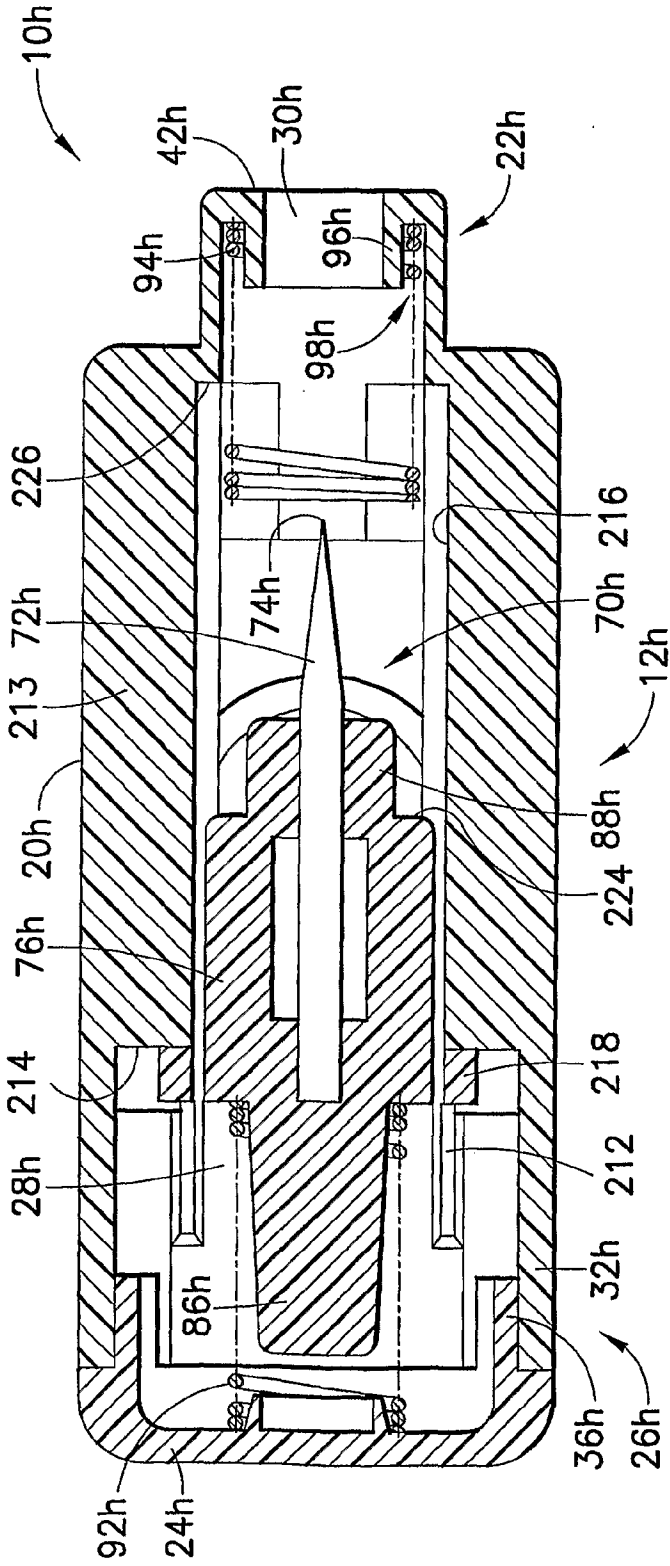


FIG.50

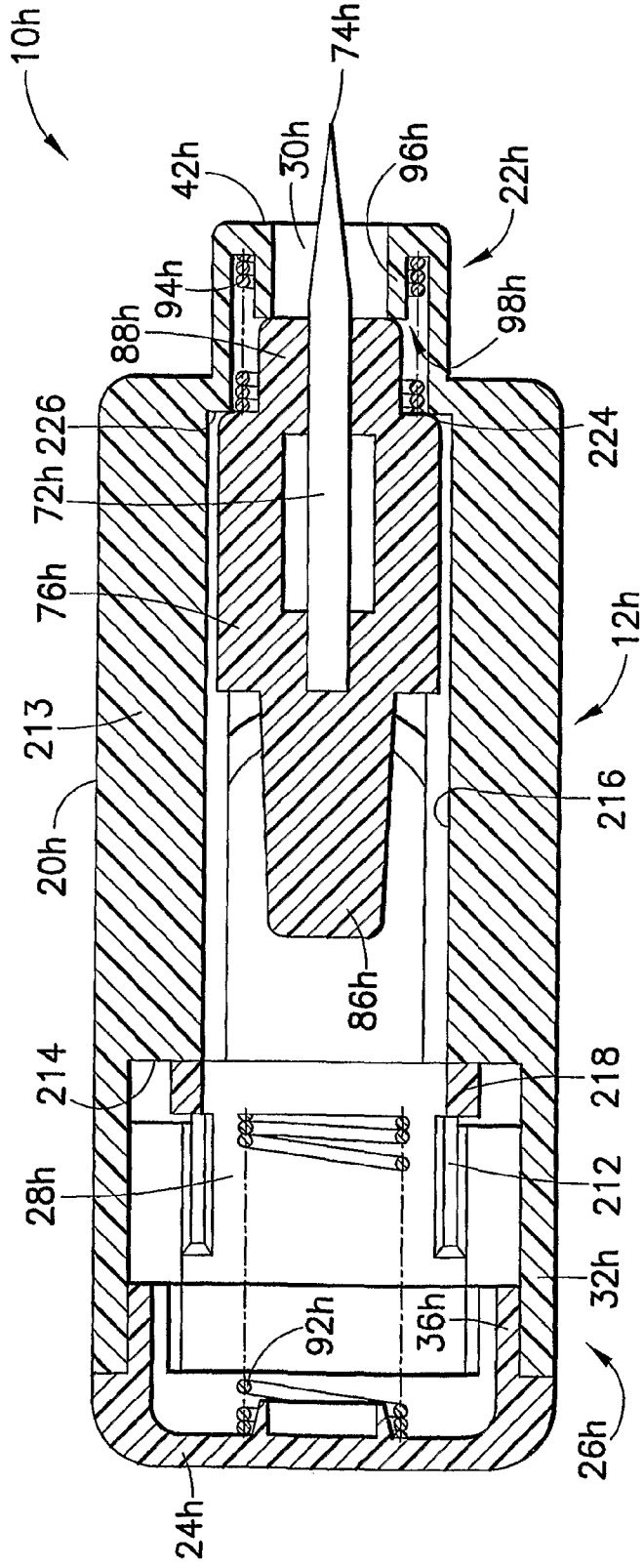


FIG.51



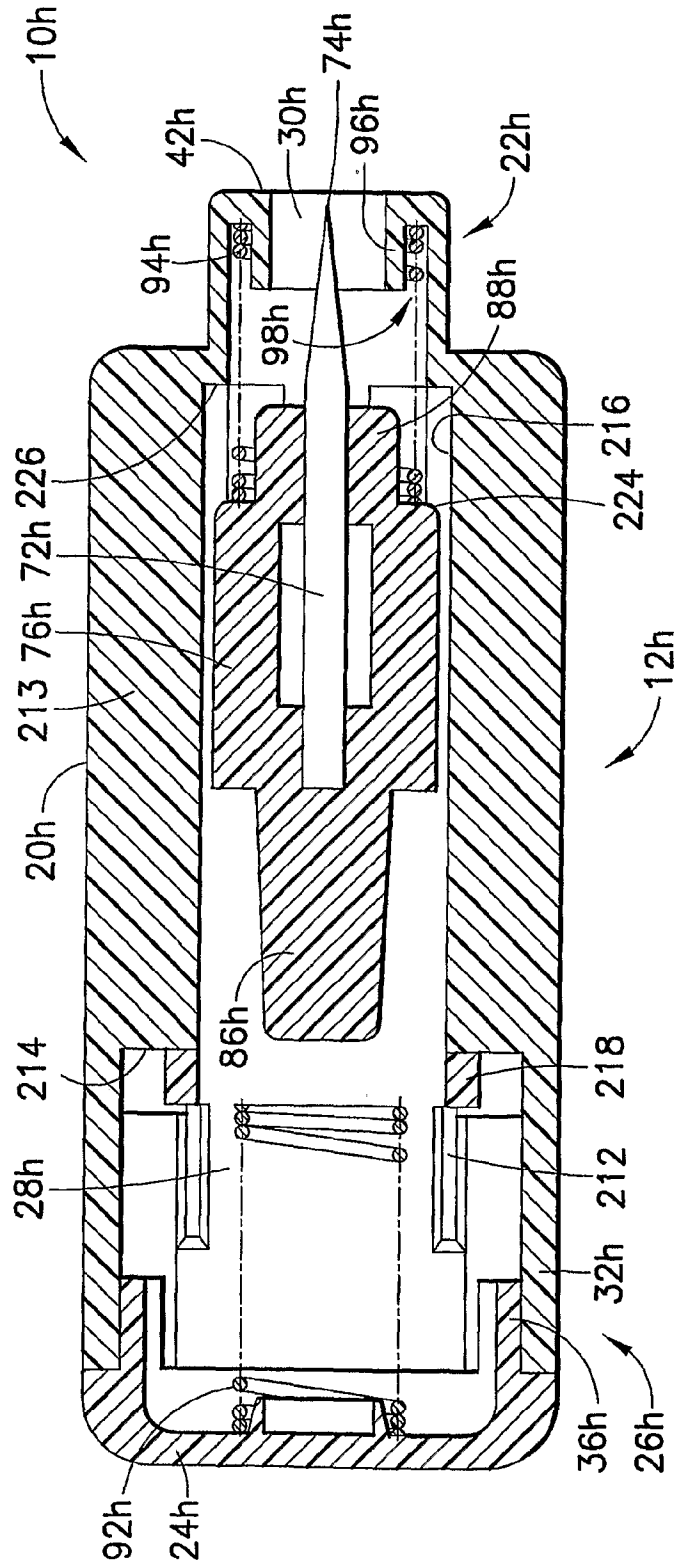


FIG. 52

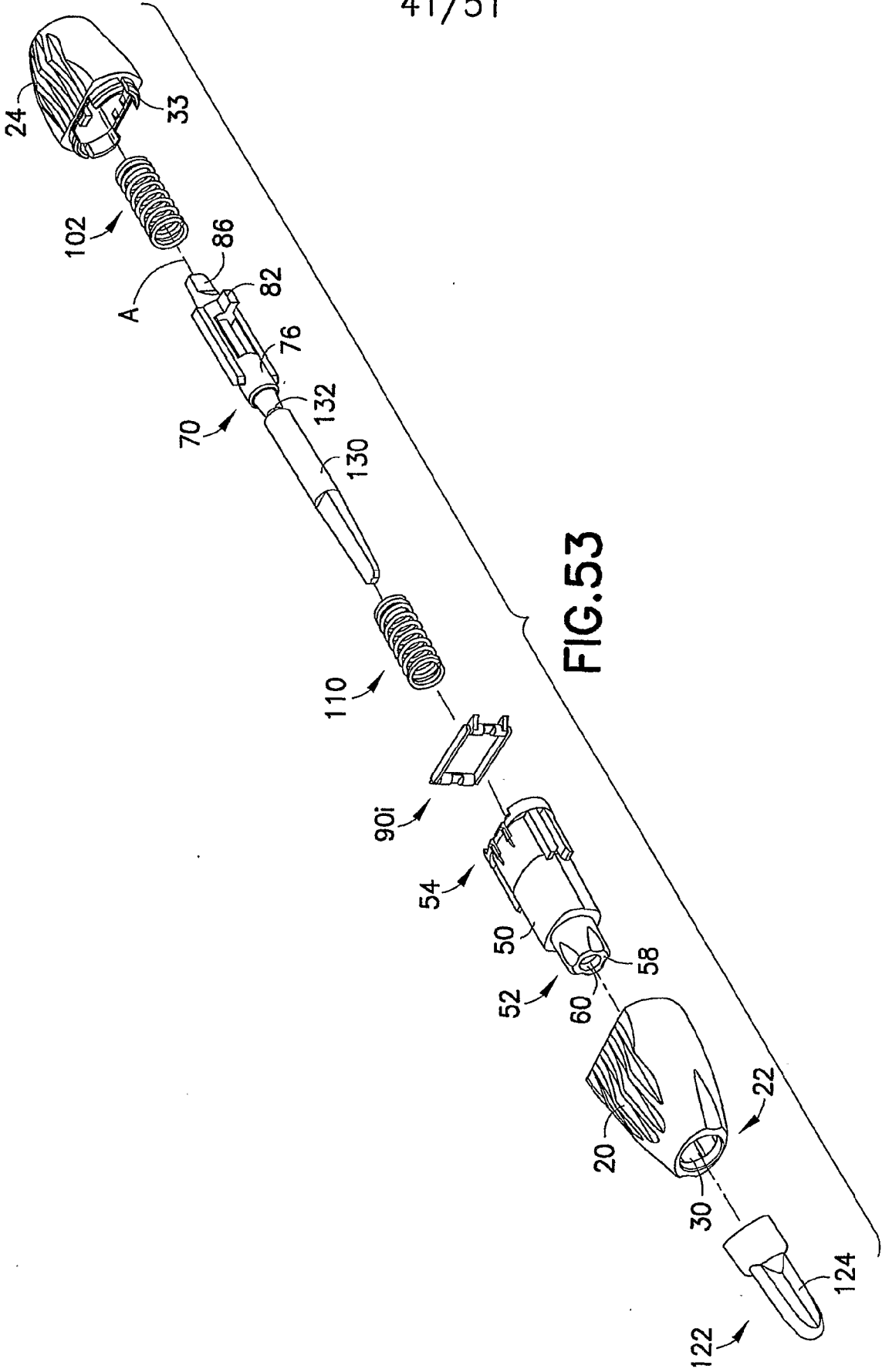


FIG.53

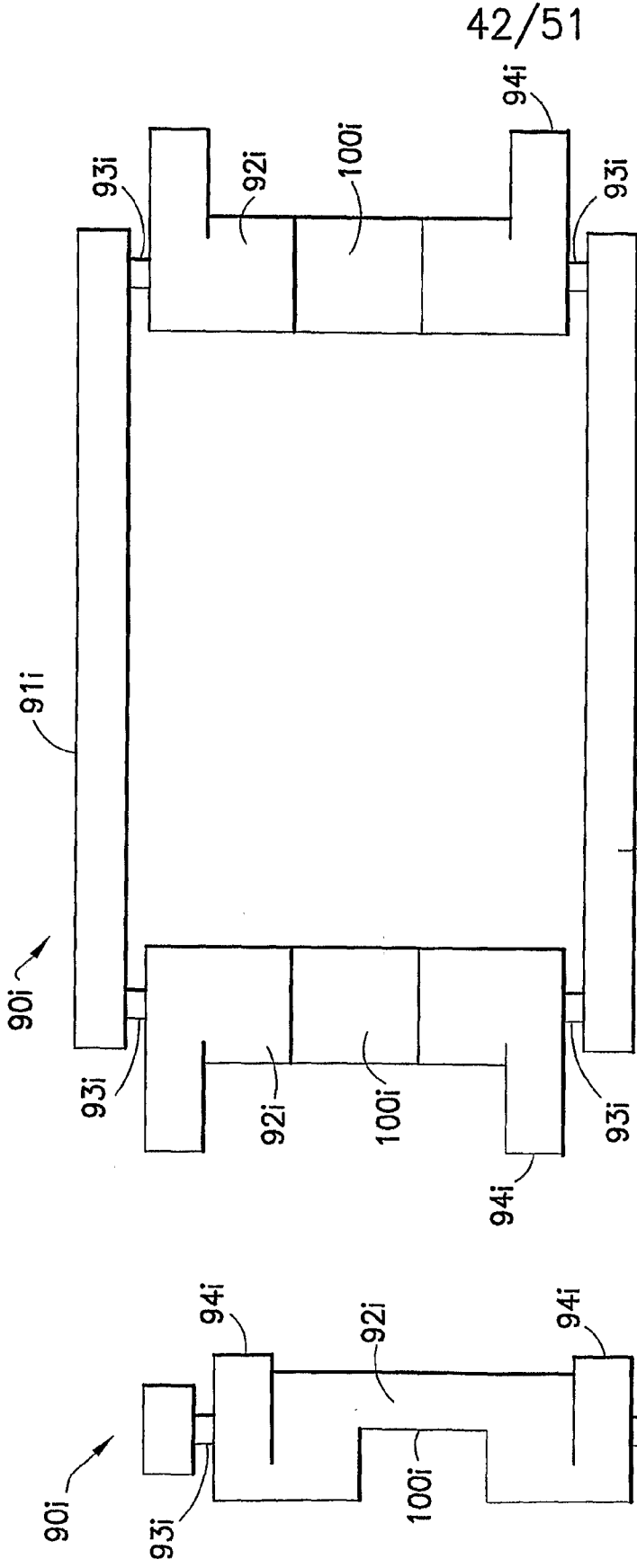


FIG. 54A

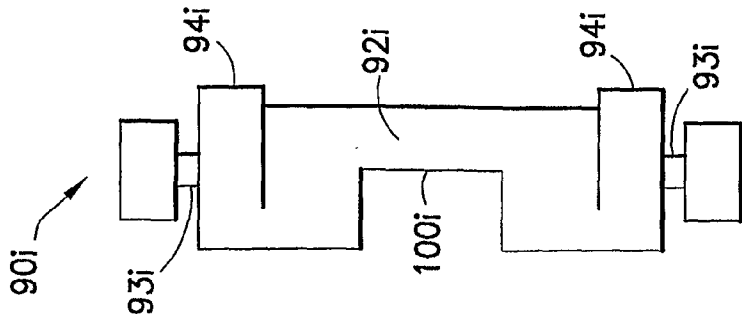


FIG. 54C

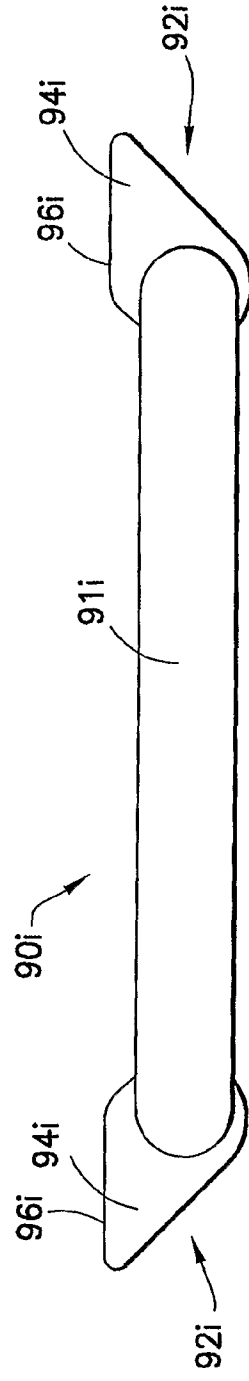


FIG. 54B

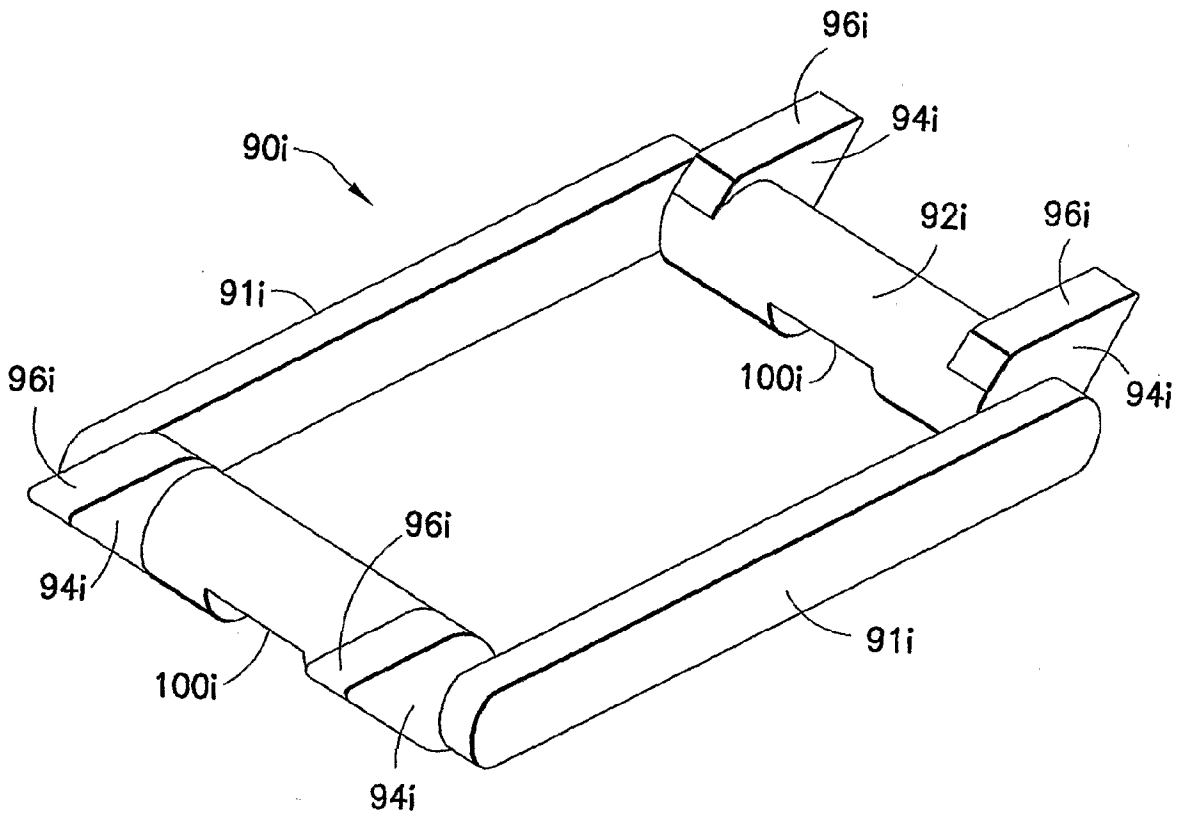


FIG.55

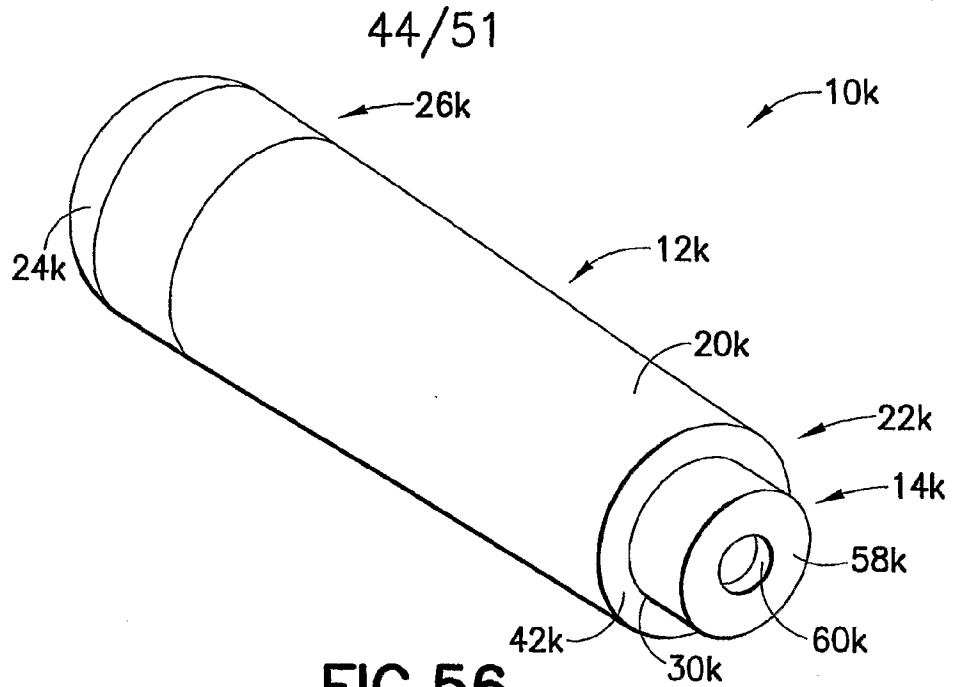


FIG. 56

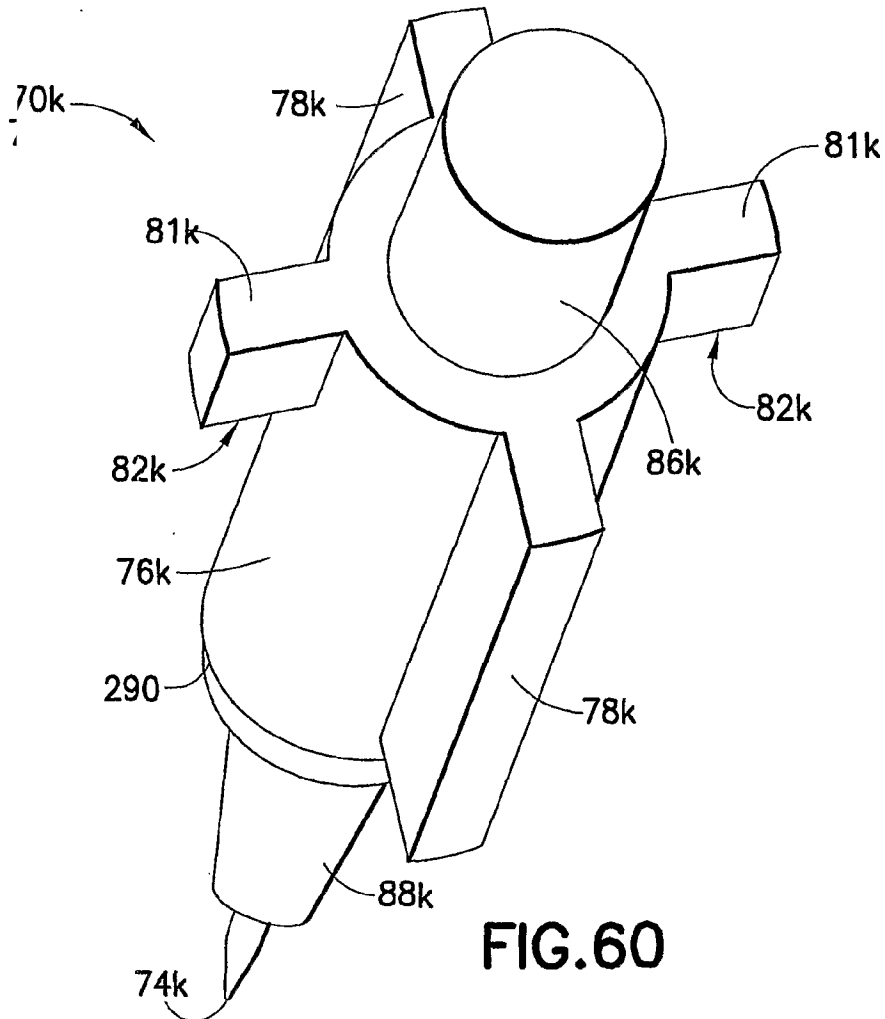


FIG. 60

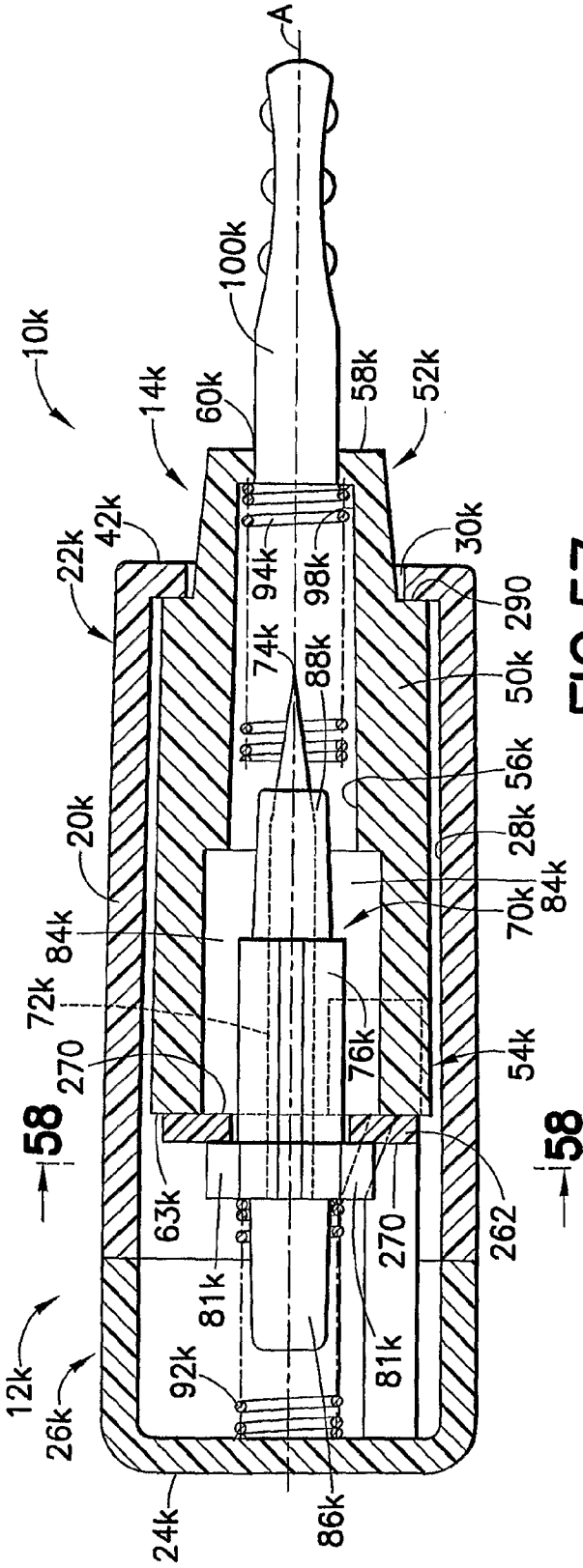


FIG. 57

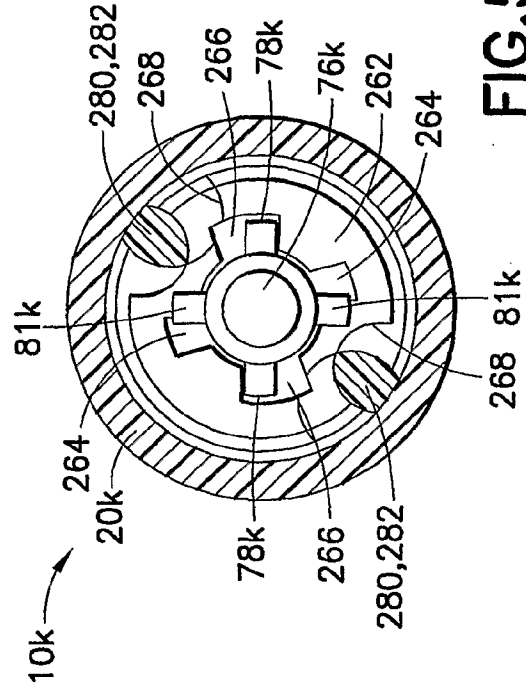


FIG. 58

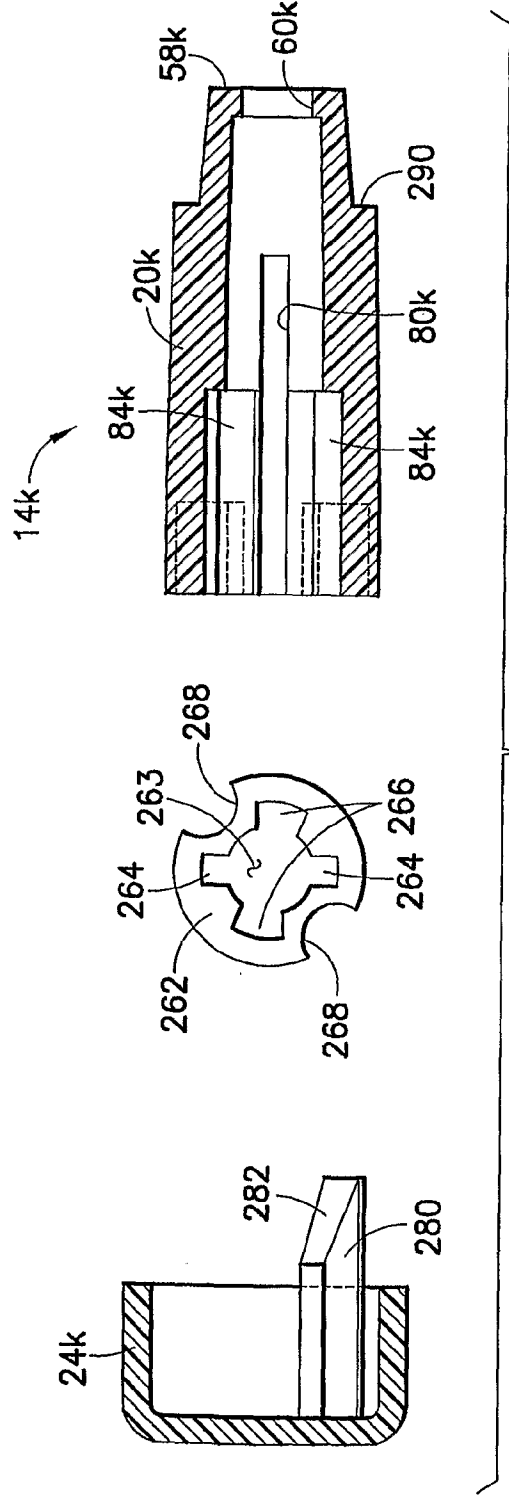


FIG.59

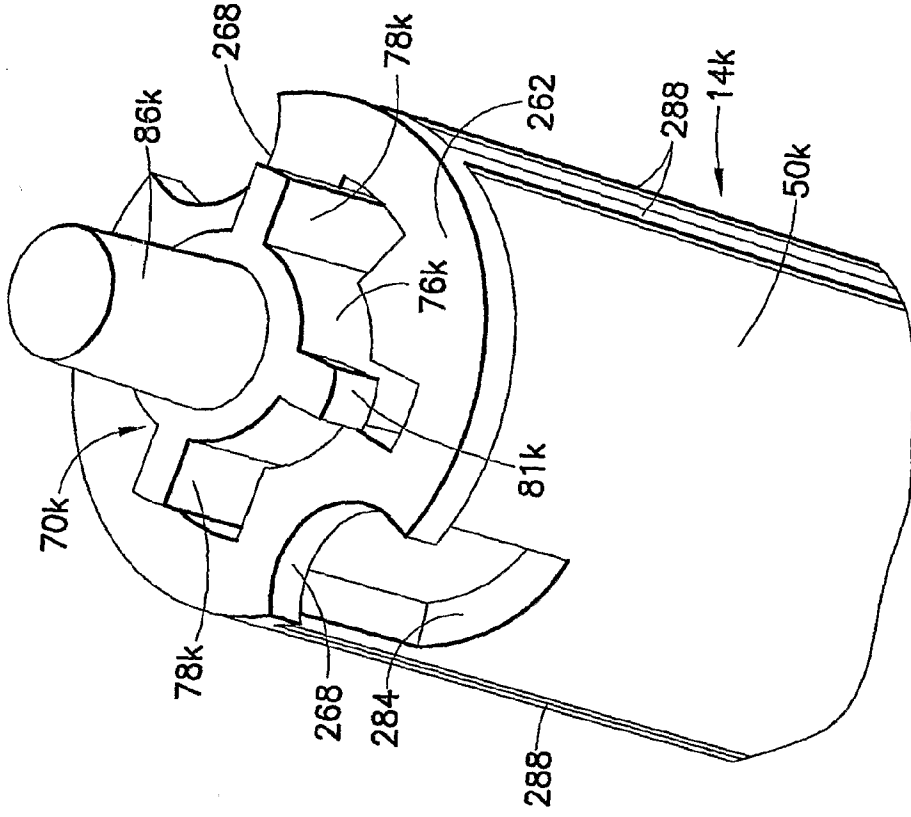


FIG. 61

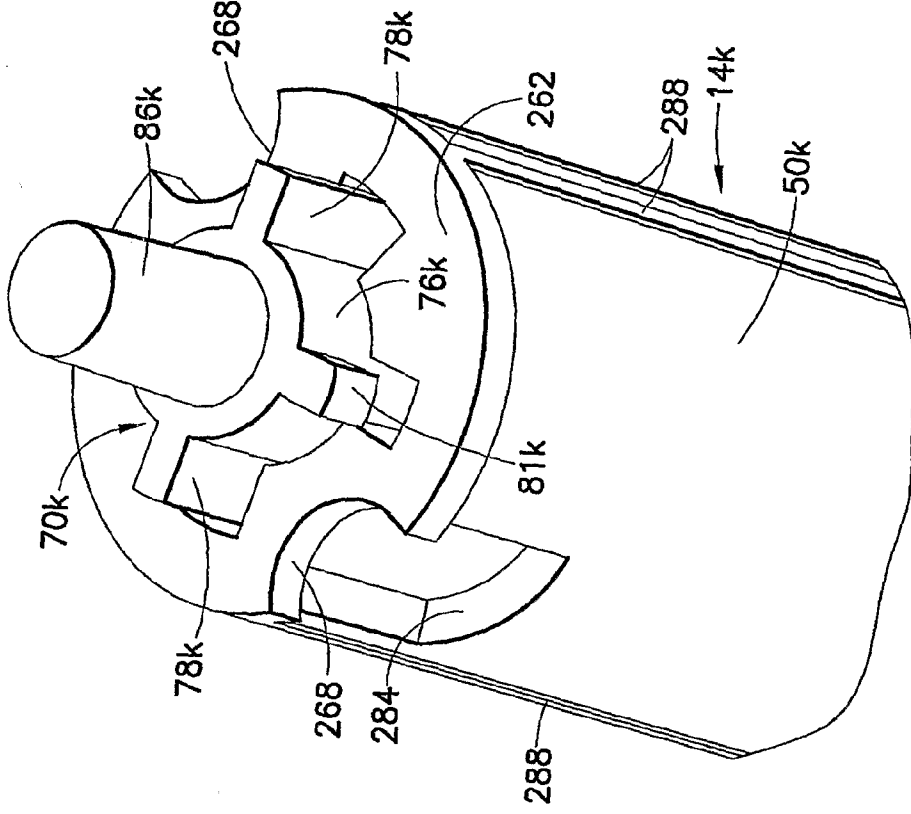


FIG. 62



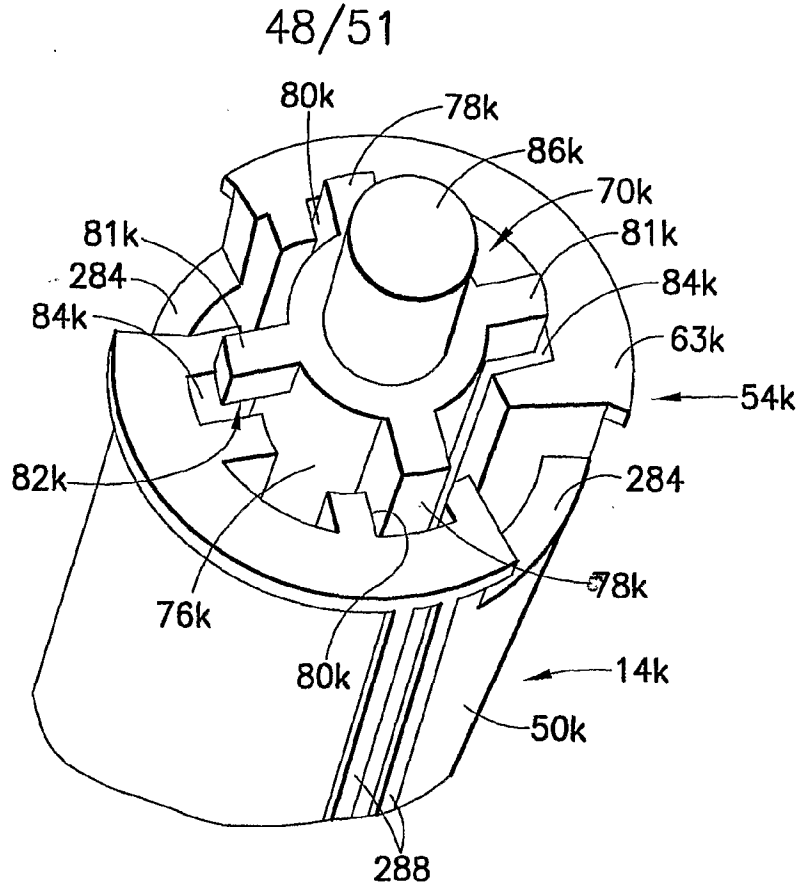


FIG. 63

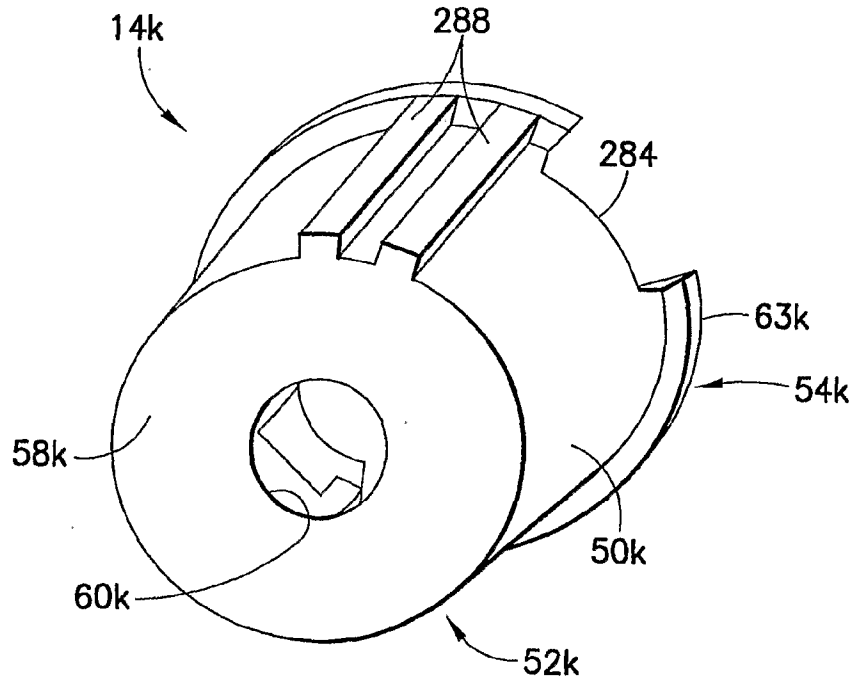


FIG. 64

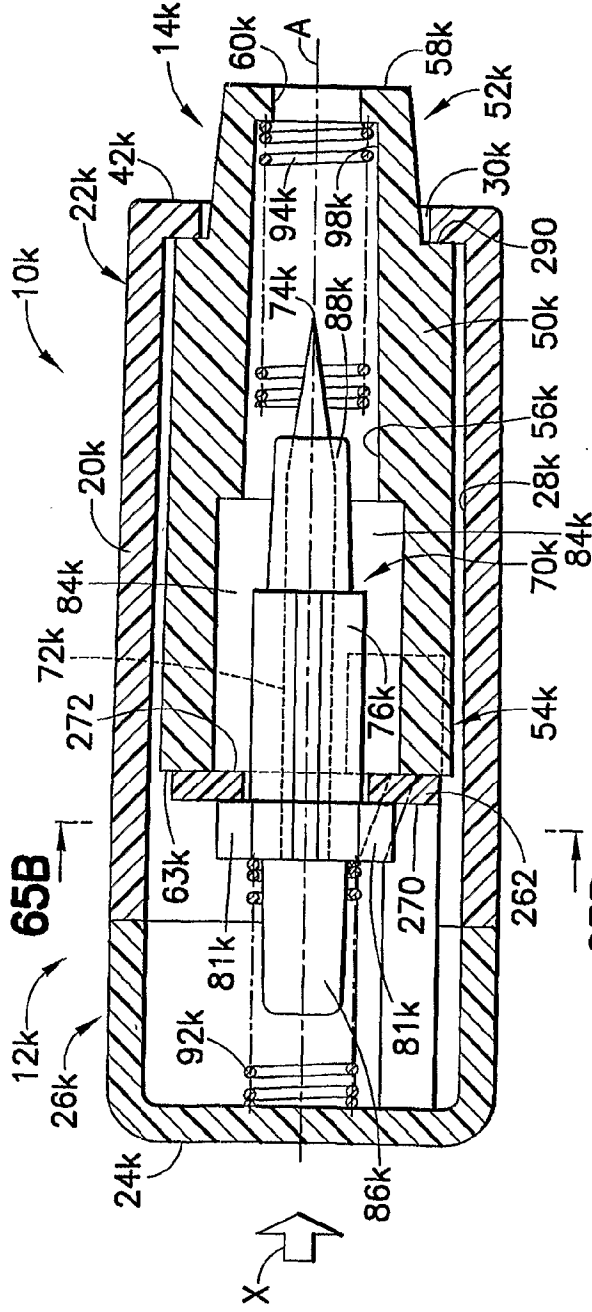


FIG. 65A

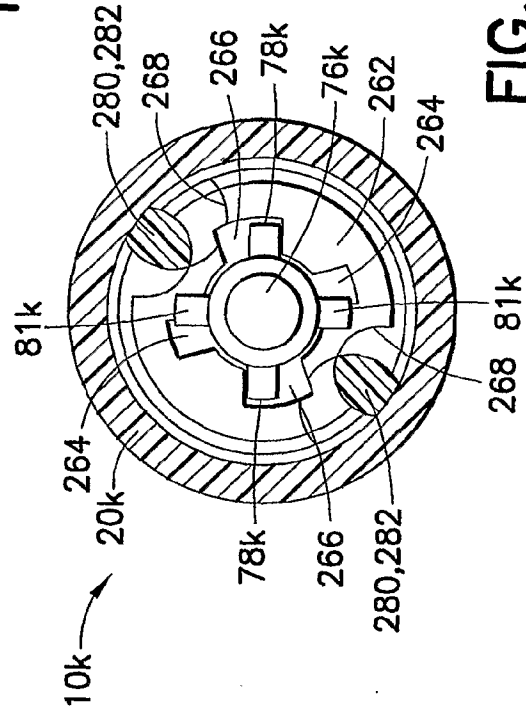


FIG. 65B

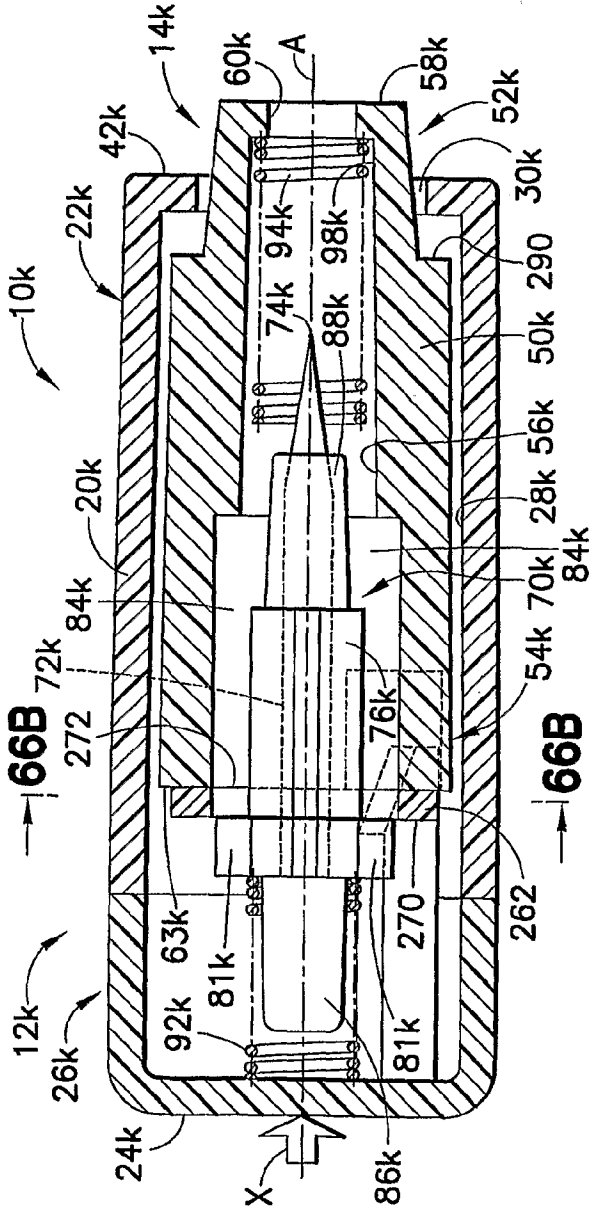


FIG. 66A

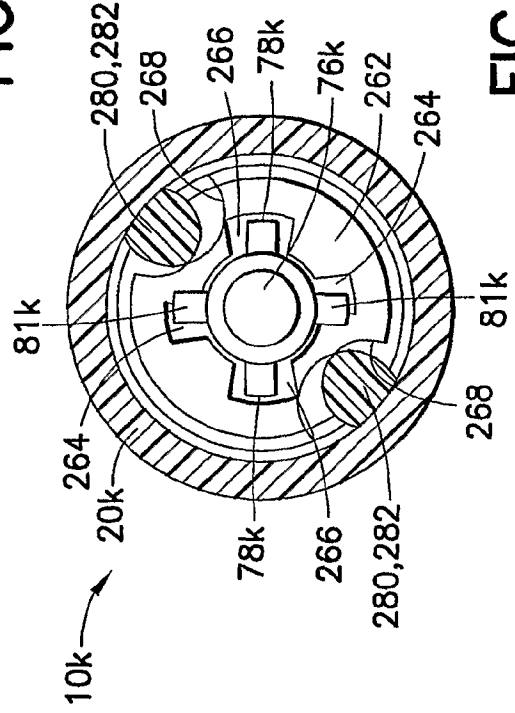


FIG. 66B

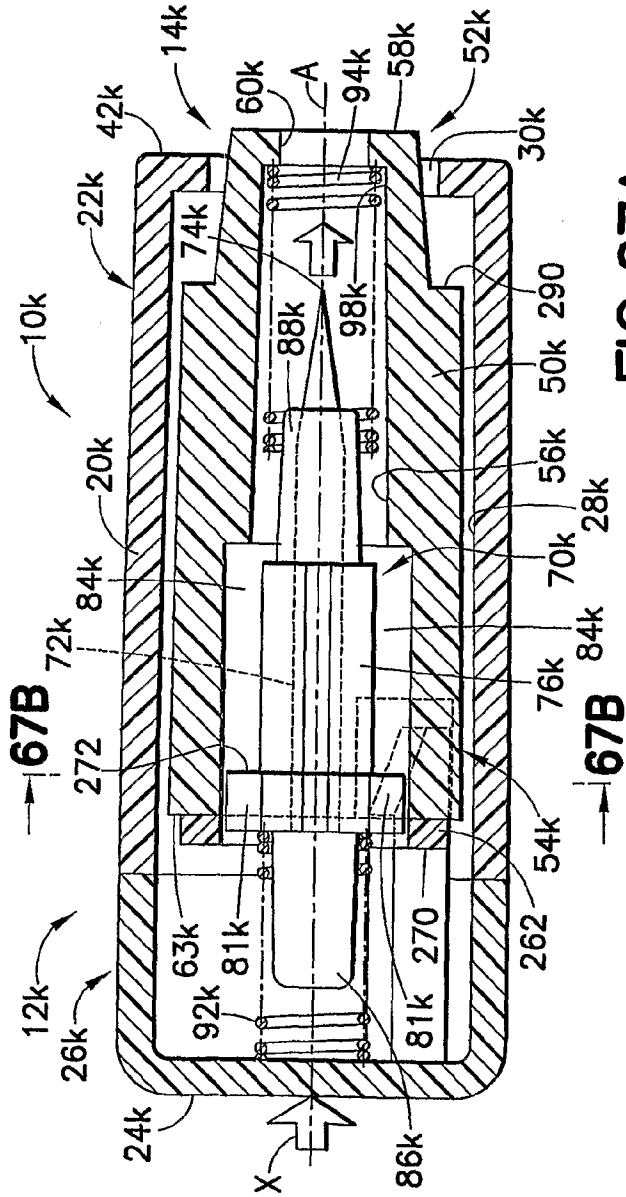


FIG. 67A

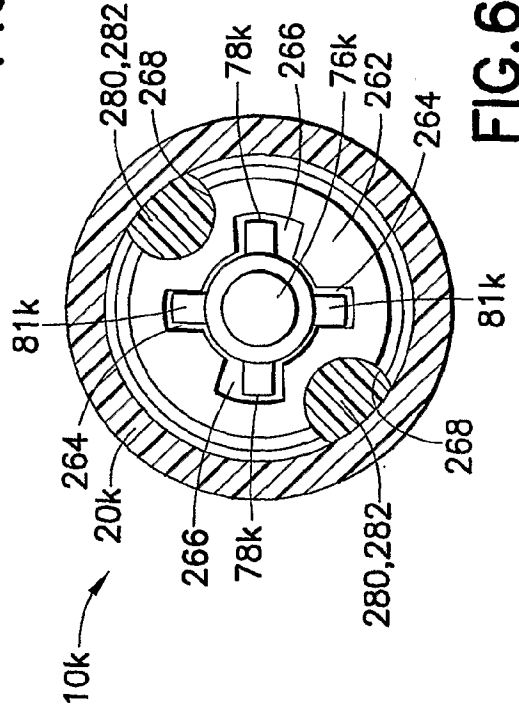


FIG. 67B