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(71) Applicant *(for all designated States except US)*: **BECTON, DICKINSON AND COMPANY** [US/US]; 1 Becton Drive, Franklin Lakes, NJ 07417-1880 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **DiCESARE, Paul** [US/US]; 68 Wells Hill Road, Easton, CT 06612 (US). **RADZIUNAS, Jeffrey** [US/US]; 1125 Durham Road, Wallingford, CT 06492 (US). **BATTLES, Christopher** [US/US]; 78 Olive Street, Apt.#432, New Haven, CT 06510 (US).

(74) Agents: **HIGHET, David, W.** et al.; Becton Dickinson and Company, 1 Becton Drive, Franklin Lakes, NJ 07417-1880 (US).

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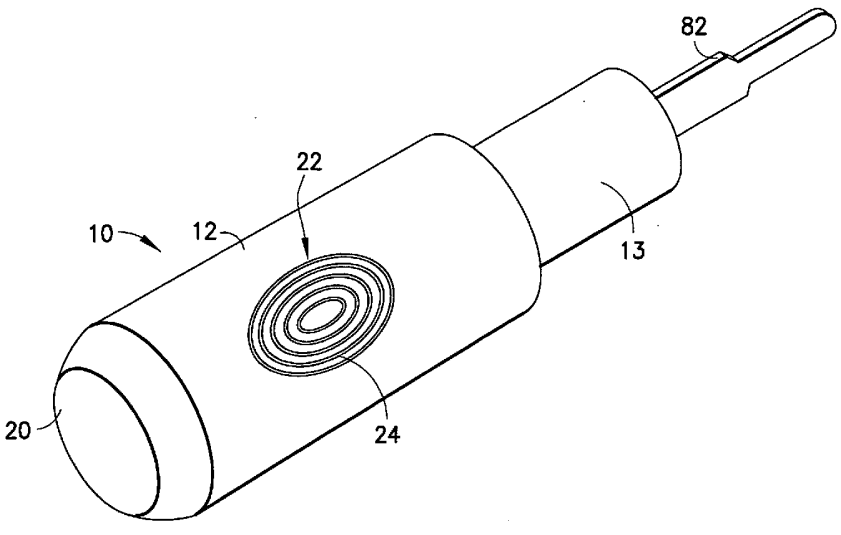
(54) Title: CAM-ACTUATED MEDICAL PUNCTURING DEVICE AND METHOD



(57) Abstract: The medical puncturing device includes a housing (12), a shield (13), and a skin puncturing assembly disposed within the housing. The shield is axially movable in the housing. The skin puncturing assembly includes a movable carrier and a skin puncturing element mounted to the carrier. A distal end of the skin puncturing element is adapted for puncturing the skin of a patient. The carrier is movable from a retracted position wherein the skin puncturing element is disposed within the shield to a puncturing position wherein the distal end of the skin puncturing element is exposed. The carrier is maintained in the retracted position by engagement of flexure members or a retaining tab with the carrier. A drive spring is provided to move the carrier from the retracted position to the puncturing position. A retraction spring is provided to return the carrier and skin puncturing element into the housing.

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CAM-ACTUATED MEDICAL PUNCTURING DEVICE AND METHOD

BACKGROUND OF THE INVENTION

Field of the Invention

The present invention relates generally to medical puncturing devices, and, more specifically, to a medical puncturing devices and methods used to take blood samples from patients.

Description of Related Art

Medical puncturing 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.

Various medical puncturing 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 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, medical puncturing devices have evolved into automatic devices that puncture or cut 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.

It is important in the medical field that such medical puncturing devices or lancets be 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 medical puncturing device/lancet design is concerned with 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 medical puncturing device or lancet 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 medical puncturing device or lancet should ideally be designed for one firing, and have safety features to prevent reuse.

Advances have been made in recent years to increase safety in operating and handling used medical puncturing devices. For example, medical puncturing 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 U.S. Patent Nos. 6,432,120; 6,248,120; 5,755,733; and 5,540,709.

U.S. Patent No. 6,432,120 to Teo discloses a lancet assembly 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. U.S. Patent No. 6,248,120 to Wyszogrodzki discloses a puncturing device comprised of a housing, 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. U.S. Patent No. 5,755,733 to Morita discloses a lancet assembly 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.

U.S. 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 U.S. Patent Nos. 4,869,249 and 4,817,603. The devices disclosed in these references include a cap that is used to protect the needle or to keep the needle sterile.

SUMMARY OF THE INVENTION

In view of the foregoing, a need generally exists in the medical field for a medical puncturing device that ensures sterility before use and safe and secure disposal after use. Additionally, a need exists in the medical field for a simple, inexpensive, reliable, self-activating, and disposable medical puncturing device for use in collecting blood samples. Moreover, there is a need for a medical puncturing device in which production of puncture wounds and/or incisions is consistent and well-controlled.

The foregoing needs are fulfilled with a medical puncturing device in accordance with embodiments of the present invention. The medical puncturing device in one embodiment generally includes a housing, a shield, a skin puncturing assembly disposed within the housing, and preferably drive and retraction springs for axially moving the skin puncturing assembly. The housing has a proximal end and a distal end. At least one flexure member extends internally in the housing. Optionally, a pair of opposing flexure members will extend internally in the housing. The shield includes a proximal end disposed within the housing and a distal end. The shield is

axially movable relative to the housing. The skin puncturing assembly includes a movable carrier and a skin puncturing element mounted to the carrier. A distal end of the skin puncturing element is adapted for puncturing the skin of a patient. The carrier is generally movable from a retracted position wherein the distal end of the skin puncturing element is disposed within the shield to a puncturing position wherein the distal end of the skin puncturing element is exposed from the shield to puncture the skin of the patient. The skin puncturing element may be a needle, for example with a sharp distal tip, or a blade with a cutting edge.

The carrier is maintained in the retracted position by engagement of the at least one flexure member with the carrier, and optionally by a pair of opposing flexure members engaged with the carrier, and moved from the retracted position to the puncturing position upon release of the at least one flexure member, or opposing flexure members, from the carrier. The drive spring is disposed within the housing, and is generally adapted to move the carrier from the retracted position to the puncturing position upon release of the at least one flexure member from the carrier. The retraction spring is disposed within the shield, and is generally adapted to return the carrier to a position within the housing wherein the shield encompasses the skin puncturing element after the carrier reaches the puncturing position.

The at least one flexure member may have a distal end engaging the carrier to maintain the carrier in the retracted position. The distal end may define a camming surface engaging an opposing camming surface on the shield proximal end, such that axial displacement of the shield into the housing causes the opposing camming surfaces to engage and release the distal end of the at least one flexure member of engagement with the carrier. More particularly, the at least one flexure member may include an inward-directed projection engaging an edge on the carrier to maintain the carrier in the retracted position. The projection may define a camming surface that engages an opposing camming surface on the shield proximal end, such that axial displacement of the shield into the housing causes the opposing camming surfaces to engage and release the projection from the carrier edge. The opposing camming surface may be oppositely tapered.

In the variation of the medical puncturing device having two opposing flexure members, distal ends of the flexure members may define tapered camming surfaces engaging an opposing, oppositely tapered camming surface on the shield proximal end. The axial displacement of the shield into the housing will cause the camming surfaces on the distal ends of the flexure members to engage the opposing, oppositely tapered camming surface on the shield proximal end and release the opposing flexure members of engagement with the carrier, permitting the drive spring to move the carrier from the retracted position to the puncturing position.

An end cap may enclose the housing proximal end. The drive spring may act between the carrier and an inner side of the end cap. The end cap may include a raised detent cooperating with a circumferential recess formed in an internal surface of the housing to connect the end cap to the housing proximal end. A removable protector cap may be provided on the shield distal end.

The shield proximal end may have at least one engagement tab adapted to engage an internal edge in the housing for limiting distal axial movement of the shield in the housing. The carrier may include at least one guide tab engaging at least one slot defined in the shield, for guiding the movement of the carrier in the shield upon release of the at least one flexure member. The at least one guide tab may be formed substantially at the carrier distal end, and the at least one slot may extend longitudinally substantially the length of the shield.

In accordance with another embodiment of the present invention, a method of actuating the medical puncturing device generally described hereinabove is provided. The method generally includes axially displacing the shield into the housing causing the distal end camming surface on the at least one flexure member to engage the opposing camming surface on the shield proximal end which releases the at least one flexure member of engagement with the carrier, such that the drive spring moves the carrier from the retracted position, wherein the distal end of the skin puncturing element is disposed within the shield, to the puncturing position, wherein the distal end is exposed from the shield to puncture the skin of the patient under the biasing force of the drive spring. Once reaching the puncturing position, the carrier is

returned to a position within the housing wherein the shield encompasses the skin puncturing element under the biasing force of the retraction spring.

As indicated previously, the distal end camming surface on the at least one flexure member and the camming surface on the shield proximal end may be oppositely tapered, such that the opposing, oppositely tapered camming surfaces engage when the shield is axially displaced into the housing, which releases the at least one flexure member of engagement with the carrier. The engagement of the opposing, oppositely tapered camming surfaces causes the at least one flexure member to flex radially out of engagement with the carrier.

The method may further include removing the protector cap from the shield distal end prior to axially displacing the shield into the housing. The at least one guide tab on the carrier may engage the at least one slot defined in the shield, such that movement of the carrier from the retracted position to the puncturing position is guided by the at least one guided tab received in the at least one slot;

In another embodiment, the medical puncturing device includes a housing, a shield, and a skin puncturing assembly disposed within the housing. The housing has a proximal end and a distal end. The shield has a proximal end and a distal end. The shield proximal end is disposed within the housing. The shield is axially movable relative to the housing. The skin puncturing assembly generally includes a movable carrier and a skin puncturing element mounted to the carrier. The skin puncturing element includes a distal tip end adapted to puncture the skin of a patient. The skin puncturing element may be a needle, for example with a sharp distal tip, or a blade with a cutting edge.

The carrier is generally movable from a retracted position wherein the distal end of the skin puncturing element is disposed within the shield to a puncturing position wherein the distal end is exposed from the shield to puncture the skin of the patient. The carrier is maintained in the retracted position by engagement of at least one retaining tab on the shield with the carrier, and moved from the retracted position to the puncturing position upon release of the retaining tab.

A drive spring may be disposed within the housing and be adapted to move the carrier from the retracted position to the puncturing position upon release of the at least one

retaining tab from the carrier. A retraction spring may be disposed within the shield and be adapted to return the carrier to a position within the housing wherein the shield encompasses the skin puncturing element after the carrier reaches the puncturing position.

The at least one retaining tab may be disposed internally in the shield and engage at least one guide tab on the carrier to maintain the carrier in the retracted position. The medical puncturing device according to this embodiment may further include an actuating member extending internally in the housing. The actuating member may define a distal end camming surface engaging an opposing camming surface on the shield proximal end, such that axial displacement of the shield into the housing causes the opposing camming surfaces to engage and release the at least one retaining tab of engagement with the at least one guide tab. The camming surface on the actuating member distal end and the camming surface on the shield proximal end may be oppositely tapered.

In accordance with another embodiment of the present invention, a method is provided for actuating the medical puncturing device described hereinabove. The method includes axially displacing the shield into the housing, which causes the distal end camming surface on the actuating member to engage the camming surface on the shield proximal end and release the at least one retaining tab of engagement with a carrier, such that the drive spring moves the carrier from the retracted position, wherein the distal end of the skin puncturing element is disposed within the shield, to the puncturing position, wherein the distal end is exposed from the shield to puncture the skin of the patient under the biasing force of the drive spring. The retraction spring may be used to return the carrier to a position within the housing, wherein the shield encompasses the skin puncturing element. The engagement of the opposing camming surfaces generally causes the shield proximal end to deform radially and release the at least one retaining tab of engagement with the at least one guide tab.

As indicated previously, the at least one retaining tab may be disposed internally in the shield and cooperate with the at least one guide tab on the carrier to maintain the carrier in a retracted position until the shield is axially displaced into the housing. The distal end camming surface on the actuating member and the opposing camming

surface on the shield proximal end may be oppositely tapered, such that the opposing, oppositely tapered camming surfaces engage when the shield is axially displaced into the housing and release the at least one retaining tab of engagement with the at least one guide tab. The engagement of the opposing, oppositely tapered camming surfaces may cause the shield proximal end to deform radially and release the at least one retaining tab of engagement with the at least one guide tab.

Further details and advantages of the present invention will become apparent from the following detailed description when read in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of a medical puncturing device in accordance with an embodiment of the present invention, showing the device with a removable tip guard;

FIG. 2 is a longitudinal cross-sectional view of the medical puncturing device of FIG. 1;

FIG. 3 is a perspective view of a housing portion of the medical puncturing device of FIG. 1, showing hidden lines;

FIG. 4 is a perspective view of a shield portion of the medical puncturing device of FIG. 1, showing hidden lines;

FIG. 5 is a perspective view of an end cap portion of the medical puncturing device of FIG. 1;

FIG. 6 is a longitudinal cross-sectional view of the medical puncturing device of FIG. 1, showing the device prior to actuation and with the tip guard removed;

FIG. 7 is a longitudinal cross-sectional view of the medical puncturing device of FIG. 1, showing the device during actuation and the direction of forces applied to actuate the device;

FIG. 8 is a longitudinal cross-sectional view of the medical puncturing device of FIG. 1, showing the device immediately after actuation with a skin piercing element of the device exposed momentarily for piercing the skin of a patient; and

FIG. 9 is a longitudinal cross-sectional view of the medical puncturing device of FIG. 1, showing the device after actuation with the skin piercing element returned to a position in the shield portion;

FIG. 10 is a longitudinal cross-sectional view of an alternative embodiment of the medical puncturing device in accordance with an embodiment of the present invention;

FIG. 11 is a perspective view of a shield portion used in the alternative embodiment of the device shown in FIG. 10; and

FIG. 12 is a perspective view of an end cap used in the alternative embodiment of the device shown in FIG. 10.

DETAILED DESCRIPTION OF THE INVENTION

For purposes of the description hereinafter, the terms "upper", "lower", "right", "left", "vertical", "horizontal", "top", "bottom", and derivatives thereof shall relate to the embodiments of the invention, as it is oriented in the drawing figures. However, it is to be understood that the embodiments may assume many alternative variations and step sequences except where expressly specified to the contrary. It is also to be understood that the specific devices and processes illustrated in the attached drawings and described in the following text are simply exemplary embodiments of the invention. Hence, specific dimensions and other physical characteristics related to the embodiments disclosed hereinafter are not to be considered limiting.

Referring to FIGS. 1-5, a medical puncturing device or lancet **10** (hereinafter "puncturing device **10**") in accordance with a first embodiment of the present invention is generally illustrated. The puncturing device **10** generally includes a housing **12**, a shield **13** received partially within and axially movable relative to the housing **12**, and a skin puncturing assembly **14** disposed within the housing **12**. The housing **12** is preferably a generally tubular structure having a distal end **16** and a proximal end **18**. The housing **12** may be open-ended at the distal and proximal ends **16**, **18**. An end cap **20** may be provided at the proximal end **16** of the housing **12** to close the proximal end **18** of the housing **12**. Alternatively, the housing **12** may be formed to have a closed proximal end **18** instead of the end cap **20**. The closed

proximal end **18** of the housing **12** would be integrally formed with the remainder of the body of the housing **12** in this variation of the puncturing device **10**.

Preferably, the housing **12** is made of a substantially rigid material such as a hard plastic, preferably a medical grade plastic. The end cap **20** may also be made of a similar material to the housing **12**. The housing **12** may have any suitable cross-sectional shape, such as oval, circular, or polygonal. However, because the housing **12** is intended to be grasped between the fingertips of the user of the puncturing device **10**, the cross-sectional shape of the housing **12** is preferably selected so that the housing **12** is easily manipulated by the user's fingertips. An oval or circular cross-sectional shape for the housing **12** best fits this requirement and is presently preferred, as depicted in FIG. 3.

Additionally, the housing **12** is preferably formed with finger pads **22** provided on opposing sides of the housing **12** for grasping by the user of the puncturing device **10**. One of the finger pads **22** as illustrated in FIG. 1, and is formed by concentric oval rings **24** that are raised from an outer or external surface **26** of the housing **12**. The fingerpads **22** provide gripping surfaces for the user of the puncturing device **10**, and also provide a tactile indication of where the user of the puncturing device **10** should place his or her fingertips when actuating the puncturing device **10** in the manner described herein. The shield **13** preferably has a cross-sectional shape that corresponds to the housing **12**, and may be circular, oval, or polygonal in transverse cross-section in a similar manner to the housing **12**. A preferred circular cross-sectional shape for the shield **13** is depicted in FIG. 4.

The housing **12** has a generally uniform wall thickness over its length up to a distal portion **28** of the housing **12**, where the wall thickness of the housing increases. The increased wall thickness of the distal portion **28** of the housing **12** forms an internal edge **30**, preferably a circumferentially-extending internal edge **30**, within the housing **12** that limits the axial distal movement of the shield **13** relative to the housing **12** as discussed herein. The increased wall thickness distal portion **28** of the housing **12** extends or forms approximately 10-40% of the length of the housing **12** and generally forms the distal end **16** of the housing **12**.

The end cap **20**, if present, is engaged with the housing **12** by a frictional, snap-fit type of engagement. Once engaged with the housing **12**, the frictional engagement between the end cap **20** and housing **12** is preferably of sufficient strength to prevent the end cap **20** from being removed easily from the housing **12** to reduce the ability of a user of the puncturing device **10** to tamper with the puncturing device **10** after manufacturing. In particular, the end cap **20** includes a circumferential detent **32** that cooperates with a circumferential recess **34** formed in an internal or interior surface **36** of the housing **12**. To further secure the connection between the end cap **20** and housing **12**, a medical-type adhesive may be provided in the recess **34** during the assembling process for the puncturing device **10**, thereby adhesively securing the detent **32** in the recess **34**. The end cap **20** further includes at least one and preferably a pair (i.e., a plurality) of opposing flexure members **38** extending internally into the housing **12** from an inner side **40** of the end cap **12**. The flexure members **38** may be integrally formed with the end cap **20**, as illustrated in FIG. 2.

The shield **13** includes a distal end **42** and a proximal end **44**. The shield **13** is disposed partially in the housing **12**, and is axially movable relative to the housing **12**. The proximal end **44** of the shield **13** is disposed within the housing **12**. As shown in FIG. 2, the distal end **42** of the shield **13** is preferably formed with an internally-extending portion **46**. The internally-extending portion **46** defines a recess or pocket **48** for housing a spring or other biasing element, as discussed further herein.

The shield **13** further includes at least one and preferably a plurality of projections or engagement tabs **49** provided or formed at the proximal end **44** of the shield **13**. The projections or engagement tabs **49** generally cooperate or engage with the internal surface **36** of the housing **12**. The engagement tabs **49** are generally further adapted to engage or contact the internal edge **30** formed by the distal portion **28** of the housing **12**. The interference engagement of the engagement tabs **49** with the internal edge **30** limits the ultimate axial distal movement of the shield **13** relative to the housing **12**, and further prevents the shield **13** from being removed from the distal end **16** of the housing **12** once inserted therein during manufacturing. The interference engagement of the engagement tabs **49** with the internal edge **30** thus minimizes the ability of a user of the puncturing device **10** to tamper with the puncturing device **10** after

manufacturing. The engagement tabs **49** may also be used to guide the movement of the shield **13** proximally into the housing **12**, and thereby function as internal guiding elements for the shield **13**. For example, the engagement tabs **49** may be configured to engage internal guide tracks/or grooves (not shown) formed internally in the housing **12**. Such internal guide tracks/or grooves, if provided, may extend from an area proximate to the end cap **20** to the distal portion **28** of the housing **12**.

As shown in FIG. 2, the skin puncturing assembly **14** is generally disposed within the housing **12** proximally of the distal portion **28** of the housing **12** and partially within the shield **13**. The skin puncturing assembly **14** is axially movable relative to the housing **12** and shield **13**. The skin puncturing assembly **14** generally includes an elongated carrier member **50** (hereinafter "carrier **50**") and a skin puncturing element **52**. The skin puncturing element **52** may be a needle, blade, or like puncturing or cutting element, and includes a sharp distal tip **54** for puncturing or cutting the skin of a patient from which a blood sample is to be taken. The carrier **50** preferably has a generally cylindrical shape to fit within the preferred circular or oval cross-sectional shape of the housing **12** and shield **13**. However, other cross-sectional shapes for the carrier **50**, such as polygonal, may be used in alternative embodiments of the present invention.

The carrier **50** includes a first or distal end **56** and a second or proximal end **58**. The distal end **56** is generally received in the shield **13** prior to actuation of the puncturing device **10**. The proximal end **58** of the carrier **50** extends toward the proximal end **18** of the housing and is generally engaged by the flexure members **38** extending from the end cap **20**. The engagement of the flexure members **38** with the carrier **50** maintains the positioning of the carrier **50** in the housing **12** and shield **13** prior to actuation of the puncturing device **10**, as discussed further herein. The body of the carrier **50** is preferably formed with at least one and preferably two or more distal guide tabs **60**. The guide tabs **60** are adapted to cooperate with respective longitudinal slots or grooves **61** formed or defined in the body of the shield **13**. The slots or grooves **61** are formed or defined internally in the shield **13**, and guide the axial distal movement of the carrier **50** relative to the shield **13** when the puncturing device **10** is actuated, as discussed further herein.

The body of the carrier **50** is also formed with a circumferentially-extending proximal protrusion or projection **62**. The proximal protrusion **62** forms a circumferential edge **64** on the body of the carrier **50** that is engaged by the flexure members **38** to maintain the positioning of the carrier **50** in the housing **12** and shield **13** prior to actuation of the puncturing device **10**. The proximal protrusion **62** preferably has a diameter no larger than the diameter of the guide tabs **60** to enable movement of the proximal end **58** of the carrier **50** into the shield **13** during actuation of the puncturing device **10**, as discussed further herein. The proximal protrusion **62** need not extend entirely around the circumference of the carrier **50**, and may be provided as two individual protrusions or projections located on opposite sides of the carrier **50** for engagement by the flexure members **38** to maintain the positioning of the carrier **50** in the housing **12** and shield **13**.

The skin puncturing element **52** generally extends from the distal end **56** of the carrier **50** and is received within a central bore **66** formed centrally within the body of the carrier **50**. The skin puncturing element **52** may be secured in the central bore **66** by a medical grade adhesive or by other means customary in the medical field. The skin puncturing element **52** is depicted in the Figures of this disclosure as a needle. However, as indicated previously, the skin puncturing element **52** is not necessarily limited to a needle or other puncturing-type element, but could also be a blade for causing an incision-type wound in the skin of a patient when the puncturing device **10** is activated.

Preferably, the carrier **50** further includes a cylindrical-shaped proximal portion **68** at the proximal end **58** of the carrier **50**. The proximal portion **68** preferably extends from the proximal protrusion **62** toward the inner side **40** of the end cap **20**. Preferably, the proximal portion **68** tapers inward toward a central axis L of the puncturing device **10**, such that the proximal portion **68** reduces in diameter toward the proximal end **58** of the carrier **50**.

The puncturing device **10** further includes a drive or firing spring **70** disposed in the housing **12** and received at least partially about the carrier **50**. The drive spring **70**, when actuated or released, provides the force necessary to move the skin puncturing assembly **14** distally within the housing **12** and through the shield **13**. The drive

spring **70** further provides the force necessary to puncture the skin of a patient when the puncturing device **10** is used in a blood-drawing or collecting procedure. More particularly, the drive spring **70** is adapted to move the carrier **50** within the housing **12** from the retracted position shown in FIG. 2 to an extended or puncturing position as shown in FIG. 8 discussed herein. In the retracted position of the carrier **50**, the sharp distal tip **54** of the skin puncturing element **52** is contained in the housing **12** and, more particularly, the shield **13**. In the extended or puncturing position, the skin puncturing element **52** extends outward from the distal end **16** of the shield **13**, and the sharp distal tip **54** of the skin puncturing element **52** is exposed for causing a puncturing or incision-type wound in the skin of a patient.

The drive spring **70** is generally received about the tapered proximal portion **68** of the carrier **50**. The tapering of the proximal portion **68** ensures that there is a tight frictional engagement between the drive spring **70** and the carrier **50**. However, the proximal portion **68** may be formed to have a substantially uniform diameter along its length, and the drive spring **70** may be secured to the proximal portion **68** by other means customary in the medical field, such as with a medical adhesive or by a simple mechanical fastener or like element. The drive spring **70** generally extends between the proximal portion **68** of the carrier **50** and the inner side **40** of the end cap **20**. The inner side **40** of the end cap **20** may include a centering protrusion or projection **72** adapted to maintain the positioning of the drive spring **70** prior to and during actuation of the puncturing device **10**. As shown in FIG. 2, the drive spring **70** is held in a compressed state within the housing **12** prior to actuation of the puncturing device **10** by the engagement of the flexure members **38** with the circumferential edge **64** formed by the proximal protrusion **62** on the carrier **50**. The drive spring **70** is generally compressed between the tapered proximal portion **68** and the inner side **40** of the end cap **20** and, optionally, between the proximal protrusion **62** on the carrier **50** and the inner side **40** of the end cap **20**.

The puncturing device **10** further includes a return or retraction spring **74** disposed in the shield **13** to provide the force necessary to generally return the skin puncturing assembly **14** to a static condition within the housing **12** and shield **13** after the puncturing device **10** is actuated by a user. More particularly, the retraction spring **74**

provides the force necessary to return the carrier **50** to a position within the housing **12** and shield **13** wherein the skin puncturing element **52** and sharp distal tip **54** thereof are fully contained within the housing **12** and shield **13**. As indicated previously, during actuation of the puncturing device **10**, the drive spring **70** generally moves the carrier **50** from the retracted position shown in FIG. 2, to an exposed or puncturing position (shown in FIG. 8 discussed herein), wherein the sharp distal tip **54** of the skin puncturing element **52** extends from the distal end **42** of the shield **13** for causing a puncturing or incision-type wound in the skin of a patient. The retraction spring **74** is used to return the carrier **50** to a position within the housing **12** and shield **13** wherein the skin puncturing element **52** and the sharp distal tip **54** thereof is fully contained within the housing **12** and shield **13**.

The retraction spring **74** is generally seated in the pocket **48** formed by the internally-extending portion **46** of the shield **13**. The retraction spring **74** generally acts on the distal end **56** of the carrier **50** as the drive spring **70** biases the carrier **50** toward the distal end **16** of the housing **12** and, further, the distal end **42** of the shield **13** when the puncturing device **10** is actuated by a user. The retraction spring **74** is in a generally uncompressed state prior to actuation of the puncturing device **10** as shown in FIG. 2. The retraction spring **74** may be secured in the pocket **48** formed by the internally-extending portion **46** of the shield **13** by a suitable medical grade adhesive, if desired. Otherwise, a simple frictional engagement between the retraction spring **74** and the pocket **48** secures the retraction spring **74** to the shield **13** in accordance with an embodiment of the present invention.

As indicated previously, the engagement of the flexure members **38** with the circumferential edge **64** formed by the proximal protrusion **62** on the carrier **50** maintains the drive spring **70** in a compressed, pre-actuated state or condition. In particular, distal ends **75** of the flexure members **38** engage the proximal protrusion **62** on the carrier **50** to maintain the drive spring **70** in the compressed, pre-actuated state. The distal end **75** of the flexure members **38** preferably include inward-directed projections **76**, which engage the circumferential edge **64** formed by the proximal protrusion **62** on the carrier **50** to maintain the drive spring **70** in the compressed, pre-actuated state. The projections **76** define engagement edges **77** that engage the

circumferential edge **64** formed by the proximal protrusion **62** on the carrier **50** to maintain the drive spring **70** in the compressed, pre-actuated state. Additionally, the projections **76** preferably further define respective camming surfaces **78**. The camming surfaces **78** are preferably tapered inward toward the central axis L of the puncturing device **10**.

As shown in FIG. 2, the distal ends **75** of the flexure members **38** are generally in contact or engagement with the proximal end **44** of the shield **13**. The proximal end **44** of the shield **13** preferably defines a tapered camming surface **80**, which engages or cooperates with the camming surfaces **78** formed at the distal ends **75** of the flexure members **38**. The camming surface **80** is preferably oppositely tapered from the camming surfaces **78**. Thus, the camming surface **80** preferably tapers away from the central axis L of the puncturing device **10**.

The skin puncturing assembly **14** may further include a protective tip guard **82** connected to the carrier **50**. The tip guard **82** may be formed integrally with the body of the carrier **50**, but include a notched connection with the distal end **56** of the carrier **50**. Alternatively, as shown in FIG. 2, the tip guard **82** may define a central bore **84**, which receives the skin puncturing element **82** and, further, the sharp distal tip **54** thereof. The tip guard **82** preferably extends outward from the distal end **16** of the housing **12** and distal end **42** of the shield **13** shown in FIGS. 1 and 2. If a notched connection is provided between the tip guard **82** and the carrier **50**, this connection enables the user of the puncturing device **10** to break the integral connection between the tip guard **82** and carrier **50**, and remove the tip guard **82** prior to actuating the puncturing device **10**. The tip guard **82** ensures that the sharp distal tip **54** of the puncturing element **52** remains sterile before use and, further, protects the user against accidental puncture wounds that could be caused by inadvertent or premature actuation of the puncturing device **10**. The tip guard **82** may be removed by simply pulling on the tip guard **82** and/or moving the tip guard **82** in a side-to-side manner in the open distal end **16** of the housing **12** until the notched connection with the carrier **50** breaks, as is well-known in the art.

The assembly of the puncturing device **10** is a simple and straight forward process. The housing **12** is typically provided first and, as discussed previously, includes the

open distal and proximal ends **16**, **18**. Next, the shield **13** preferably containing the retraction spring **74** may be inserted into the open proximal end **18** of the housing **12**, such that the distal end **42** of the shield **13** extends from the distal end **16** of the housing **12**. The engagement of the engagement tabs **49** with the internal edge **30** defined by the distal portion **28** of the housing **12** limits the distal movement of the shield **13** relative to the housing **12**. Once the shield **13** is in place, the skin puncturing assembly **14** may be inserted into the open proximal end **18** of the housing **12**. The skin puncturing assembly **14** is generally inserted into the housing **12** so that the distal guide tabs **60** slidably cooperate with the longitudinal slots **61** formed in the shield **13**.

With the skin puncturing assembly **14** in place within the housing **12** and shield **13**, the drive spring **70** may be inserted into the housing **12** through the open proximal end **18** of the housing **12**. The drive spring **70** is received about the tapered proximal portion **68** of the carrier **50** and extends from the tapered proximal portion **68** towards the open proximal end **18** of the housing **12**. The housing proximal end **18** is then closed with the end cap **20**. The drive spring **70** is generally placed in a compressed, pre-actuated state within the housing **12** by affixing the end cap **20** to the housing proximal end **18**. In particular, the flexure members **38** are placed in engagement with the proximal protrusion **62** on the carrier **50** which compresses the drive spring **70** about the carrier **50**. The end cap **20** is secured to the housing **12** by engagement of the detent **32** on the end cap **20** with the recess **34** in the housing **12**. The assembled puncturing device **10** is now ready for use.

Referring to FIGS. 6-9, the sequence of actuation for the puncturing device **10** will now be discussed. FIG. 6 shows the puncturing device **10** in a pre-actuated state in a similar manner to FIG. 4 discussed previously but with the tip guard **82** removed. In the pre-actuated state, the flexure members **38** are in engagement with the carrier **50**. The engagement of the flexure members **38** with the carrier **50** maintains the drive spring **70** in a compressed state between the end cap **20** and the proximal portion **68** of the carrier and, optionally, between the end cap **20** and the proximal protrusion **62**. Additionally, in the pre-actuated state, the retraction spring **74** is disposed in the

pocket **24** formed at the distal end **42** of the shield **13** and is in an uncompressed or untensioned state.

To actuate the puncturing device **10**, the user grasps the housing **12** between the thumb and forefinger, preferably with the thumb and forefinger substantially engaging the fingerpads **22** on the external surface **26** of the housing **12**. The user then places the distal end **42** of the shield **13** in contact with the body part where a blood sample is to be taken. The user exerts a distally-directed force on the housing **12**, which causes the shield **13** to move proximally into the housing **12** in the direction of arrows **90** in FIG. 6. This simultaneously causes the proximal end **44** of the shield **13** to contact or engage the flexure members **38**. In particular, the camming surface **80** on the proximal end **44** of the shield **13** engages the camming surfaces **78** on the inward-directed projections **76** of the flexure members **38**, which causes the flexure members **38** to move or spread radially apart, as represented by arrows **92** in FIG. 7. Once the interference engagement between the flexure members **38** and the proximal protrusion **62** on the carrier **50** is released, the compressed drive spring **70** is also released. The drive spring **70** automatically biases or drives the carrier **50** toward the distal end **16** of the housing **12** and distal end **42** of the shield **13**. The engagement of the distal guide tabs **60** on the carrier **50** with the longitudinal slots **61** in the shield **13** guides the movement of the carrier **50** in the housing **12** and in the shield **13**.

FIG. 8 shows the released movement of the carrier **50** in the housing **12** and shield **13**. The carrier **50** is released from the retracted position or configuration shown in FIG. 6 and moves to a puncturing position or configuration shown in FIG. 8, wherein the puncturing element **52** extends from the distal end **42** of the shield **13** and the sharp distal tip **54** of the puncturing element **52** is fully exposed for piercing or cutting the skin of a patient. The direction of movement of the carrier **50** in the housing **12** and shield **13** upon actuation of the puncturing device **10** is identified by arrow **94** in FIG. 8. In the puncturing position or configuration shown in FIG. 8, the skin puncturing element **52** of the skin puncturing assembly **14** reaches its maximum extension from the distal end **42** of the shield **13** and is driven under the force of the drive spring **70** into the skin of the patient (not shown). The drive spring **70** preferably has sufficient stored energy to cause the sharp distal tip **54** of the skin puncturing element **52** to

pierce the skin of a person or animal once the flexure members **38** are released of engagement with the carrier **50**.

FIG. 9 shows the ultimate disposition of the carrier **50** within the housing **12** and shield **13** after the puncturing device **10** has been actuated. As shown in FIG. 8, as the carrier **50** reaches the puncturing position wherein the sharp distal tip **54** of the skin puncturing element **52** is fully exposed, the retraction spring **74** is compressed between the distal guide tabs 60 on the carrier **50** and the distal end **42** of the shield **13**. The retraction spring **74** is compressed in the pocket **48**. The compression of the retraction spring **74** provides a return or retraction force that acts on the carrier **50** to move the carrier **50** in a return or retraction direction in the housing **12** as identified with arrow **96** in FIG. 9, which returns or retracts the skin puncturing element **52** and the sharp distal tip **54** thereof fully into the housing **12** and shield **13**. The retraction spring **74** thereafter prevents the reemergence of the skin puncturing element **52** from the housing **12** and shield **13**. If desired, a protector cap **98** may be provided to enclose the distal end **42** of the shield **13** to further ensure that the skin puncturing element **52** will not extend outward from the shield **13** after the puncturing device **10** has been activated. The protector cap **98** is removable from the shield **13** and may generally take the place of the tip guard **82** discussed previously. Thus, the removable protector cap **98** may be provided on the distal end **42** of the shield **13** prior to actuation of the puncturing device **10** and reapplied or replaced thereon after the puncturing device **10** has been actuated.

Referring to FIGS. 10-12, another embodiment of the puncturing device **10** is shown. In the puncturing device **10**, the carrier member **50** is no longer maintained in the retracted position by the flexure members **38**. In the puncturing device **10** illustrated in FIGS 10-12, one or more retaining tabs **100** is provided internally in the shield **13**. The retaining tabs **100** maintain the positioning of the carrier **50** in the shield **13**, and, further, compression of the drive spring **70** until actuation of the puncturing device **10**. The flexure members **38** previously provided on the end cap **40** are now replaced or formed as a singular actuating member **101** extending from the end cap **40**.

The puncturing device **10** shown in FIGS 10-12 is actuated in a slightly different manner than the puncturing device **10** illustrated in FIGS 1-9. The proximal end **44** of

the shield is now adapted to be radially deformed or flexed outward by the distal ends **75** of preferably the singular actuating member **101** when the shield **13** is axially displaced into the housing **12**. To provide for this outward radial displacement, the proximal end **44** of the shield **13** defines at least one and, preferably, at least two opposing slots **102, 104**. The proximal end **44** of the shield **13** also extends further into the housing **12**, as shown in FIG. 10. The camming surface **80** on the proximal end **44** of the shield **13** is also tapered in an opposite direction from the configuration used in the puncturing device **10** discussed previously in connection with FIGS. 1-9.

In the puncturing device **10** illustrated in Figs. 10-12 the distal end **44** of the actuating member **101** defines a camming surface **78** that is oppositely tapered from the camming surfaces **78** on the distal ends **75** of the flexure members **38** discussed previously in connection with FIGS. 1-9. The actuating member **101** is now adapted to engage the proximal end **44** of the shield **13** and radially deform or flex the proximal end **44** of the shield **13** to permit the drive spring **70** to move the carrier **50** within the housing **12** and shield **13**. In particular, the camming surface **78** on the distal end **75** of the actuating member **101** engages the oppositely tapered and opposing camming surface **80** on the proximal end **44** of the shield **13**, such that the proximal end **44** of the shield **13** deforms or flexes radially outward by virtue of the slots **102, 104** when the shield is displaced into the housing **12**. The opposing camming surfaces **78, 80** are preferably configured to deform the proximal end **44** of the shield **13** sufficiently radially outward, which is facilitated by the opposing slots **102, 104**, to release the retaining tabs **100** from engagement with the carrier **50**. In particular, the retaining tabs **100** are released of engagement with the guide tabs **60** formed on the carrier **50** proximate to the distal end **56** of the carrier **50**. Once the retaining tabs **100** are released of engagement, the carrier **50** will be displaced by the drive spring **70** in the manner discussed previously in connection with the puncturing device **10** illustrated in FIGS 2-9. Other than the specific changes discussed hereinabove, the puncturing device **10** shown in FIGS 10-12 is identical in all other respects to the puncturing device **10** discussed previously in connection with FIGS. 2-9.

While the present invention was described with reference to preferred embodiments of the medical puncturing device, those skilled in the art may make modifications and alterations to the present 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.

WHAT IS CLAIMED:

1. A medical puncturing device, comprising:

a housing having a proximal end and a distal end, the housing comprising at least one flexure member extending internally therein;

a shield having a proximal end and a distal end, the shield proximal end disposed within the housing, and the shield axially movable relative to the housing;

a skin puncturing assembly disposed within the housing and comprising a movable carrier and a skin puncturing element integral with the carrier, a distal end of the skin puncturing element adapted for puncturing the skin of a patient, the carrier movable from a retracted position wherein the distal end of the skin puncturing element is disposed within the shield to a puncturing position wherein the distal end is exposed from the shield to puncture the skin of the patient, the carrier maintained in the retracted position by engagement of the at least one flexure member with the carrier and moved from the retracted position to the puncturing position upon release of the at least one flexure member from the carrier;

a drive spring disposed within the housing, the drive spring adapted to move the carrier from the retracted position to the puncturing position upon release of the at least one flexure member from the carrier; and

a retraction spring disposed within the shield, the retraction spring adapted to return the carrier to a position within the housing wherein the shield encompasses the skin puncturing element after the carrier reaches the puncturing position.

2. The medical puncturing device of claim 1, wherein the at least one flexure member comprises an inward-directed projection engaging an edge on the carrier to maintain the carrier in the retracted position.

3. The medical puncturing device of claim 2, wherein the projection defines a camming surface and the shield proximal end defines an opposing camming

surface, and wherein axial displacement of the shield into the housing causes the opposing camming surfaces to engage and release the projection from the carrier edge.

4. The medical puncturing device of claim 1, wherein the at least one flexure member comprises a distal end engaging the carrier to maintain the carrier in the retracted position, wherein the distal end defines a camming surface engaging an opposing camming surface on the shield proximal end, and wherein axial displacement of the shield into the housing causes the opposing camming surfaces to engage and release the distal end of the at least one flexure member of engagement with the carrier.

5. The medical puncturing device of claim 1, further comprising an end cap enclosing the housing proximal end, the drive spring acting between the carrier and an inner side of the end cap.

6. The medical puncturing device of claim 5, wherein the end cap comprises a raised detent cooperating with a circumferential recess formed in an internal surface of the housing to connect the end cap to the housing proximal end.

7. The medical puncturing device of claim 1, wherein the shield proximal end comprises at least one engagement tab adapted to engage an internal edge formed in the housing for limiting distal axial movement of the shield in the housing.

8. The medical puncturing device of claim 1, wherein the carrier comprises at least one guide tab engaging at least one slot defined in the shield for guiding movement of the carrier in the shield upon release of the at least one flexure member.

9. The medical puncturing device of claim 8, wherein the at least one guide tab is formed substantially at the carrier distal end and the at least one slot extends longitudinally substantially the length of the shield.

10. A medical puncturing device, comprising:

a housing having a proximal end and a distal end;

a shield having a proximal end and a distal end, the shield proximal end disposed within the housing, and the shield axially movable relative to the housing; and

a skin puncturing assembly disposed within the housing and comprising a movable carrier and a skin puncturing element integral with the carrier, a distal end of the skin puncturing element adapted for puncturing the skin of a patient, the carrier movable from a retracted position wherein the distal end of the skin puncturing element is disposed within the shield to a puncturing position wherein the distal end is exposed from the shield to puncture the skin of the patient, the carrier maintained in the retracted position by engagement of at least one retaining tab on the shield with the carrier and moved from the retracted position to the puncturing position upon release of the at least one retaining tab from the carrier.

11. The medical puncturing device of claim 10, further comprising a drive spring disposed within the housing, the drive spring adapted to move the carrier from the retracted position to the puncturing position upon release of the at least one retaining tab from the carrier.

12. The medical puncturing device of claim 10, further comprising a retraction spring disposed within the shield, the retraction spring adapted to return the carrier to a position within the housing wherein the shield encompasses the skin puncturing element after the carrier reaches the puncturing position.

13. The medical puncturing device of claim 10, wherein the at least one retaining tab is disposed internally in the shield and engages at least one guide tab on the carrier to maintain the carrier in the retracted position.

14. The medical puncturing device of claim 10, further comprising an end cap enclosing the housing proximal end.

15. The medical puncturing device of claim 14, wherein the end cap comprises a raised detent cooperating with a circumferential recess formed in an internal surface of the housing to connect the end cap to the housing proximal end.

16. The medical puncturing device of claim 10, wherein the shield proximal end comprises at least one engagement tab adapted to engage an internal edge formed in the housing for limiting distal axial movement of the shield in the housing.

17. The medical puncturing device of claim 10, wherein the carrier comprises at least one guide tab engaging at least one slot defined in the shield for guiding movement of the carrier in the shield upon release of the at least one retaining tab from the carrier.

18. A medical puncturing device, comprising:

a housing having a proximal end and a distal end, the housing comprising a pair of opposing flexure members extending internally therein;

a shield having a proximal end and a distal end, the shield proximal end disposed within the housing, the shield axially movable relative to the housing;

a skin puncturing assembly disposed within the housing and comprising a movable carrier and a skin puncturing element integral with the carrier, a distal end of the skin puncturing element adapted for puncturing the skin of a patient, the carrier movable from a retracted position wherein the distal end of the skin puncturing element is disposed within the shield to a puncturing position wherein the distal end is

exposed from the shield to puncture the skin of the patient, the carrier maintained in the retracted position by engagement of the opposing flexure members with the carrier and moved from the retracted position to the puncturing position upon release of the opposing flexure members from the carrier;

a drive spring disposed within the housing, the drive spring adapted to move the carrier from the retracted position to the puncturing position upon release of the opposing flexure members from the carrier; and

a retraction spring disposed within the shield, the retraction spring adapted to return the carrier to a position within the housing wherein the shield encompasses the skin puncturing element after the carrier reaches the puncturing position;

wherein the opposing flexure members have distal ends engaging the carrier to maintain the carrier in the retracted position, and wherein the distal ends of the opposing flexure members define tapered camming surfaces engaging an opposing, oppositely tapered camming surface on the shield proximal end, the engagement of the opposing camming surfaces adapted to spread the opposing flexure members radially outward upon axial displacement of the shield into the housing, such that the opposing flexure members are released of engagement with the carrier permitting the drive spring to move the carrier from the retracted position to the puncturing position.

19. A medical puncturing device, comprising:

a housing having a proximal end and a distal end, the housing comprising an actuating member extending internally therein;

a shield having a proximal end and a distal end, the shield proximal end disposed within the housing, and the shield axially movable relative to the housing;

a skin puncturing assembly disposed within the housing and comprising a movable carrier and a skin puncturing element integral with the carrier, a distal end of the skin puncturing element adapted for puncturing the skin of a patient, the carrier movable from a retracted position wherein the distal end of the skin puncturing element is disposed within the shield to a puncturing position wherein the distal end of

the skin puncturing element is exposed from the shield to puncture the skin of the patient, the carrier maintained in the retracted position by engagement of at least one retaining tab on the shield with the carrier and moved from the retracted position to the puncturing position upon release of the at least one retaining tab from the carrier;

a drive spring disposed within the housing, the drive spring adapted to move the carrier from the retracted position to the puncturing position upon release of the at least one retaining tab from the carrier; and

a retraction spring disposed within the shield, the retraction spring adapted to return the carrier to a position within the housing wherein the shield encompasses the skin puncturing element after the carrier reaches the puncturing position;

wherein the actuating member has a distal end defining a tapered camming surface engaging an opposing, oppositely tapered camming surface on the shield proximal end, the engagement of the opposing camming surfaces adapted to radially deform the shield proximal end upon axial displacement of the shield into the housing, such that the at least one retaining tab is released of engagement with the carrier permitting the drive spring to move the carrier from the retracted position to the puncturing position.

20. A medical device comprising:

a carrier comprising a puncture element,

a housing; and

a shield internally movable with respect to said housing;

wherein said housing comprises a distally extending flexural element, said flexural element comprises a carrier latch;

wherein the shield comprises a proximally extending cam to engage said flexural element;

wherein the carrier comprises a surface for releaseably cooperating with said carrier latch; and

wherein movement of said shield internally to said housing causes said flexural element to release said carrier latch from cooperation with said carrier.

21. The medical device of claim 20, wherein said cam substantially resists flexure during engagement with said flexural element.

22. A method of actuating a medical puncturing device comprising:

providing a medical device having

a housing comprising at least one flexure member extending internally therein;

a shield having a proximal end disposed in the housing and axially movable relative to the housing;

a skin puncturing assembly disposed within the housing and comprising a movable carrier and a skin puncturing element mounted to the carrier, a distal end of the skin puncturing element adapted to puncture the skin of a patient;

a drive spring disposed within the housing and adapted to move the carrier in the shield; and

a retraction spring disposed within the shield;

wherein the at least one flexure member engages the carrier, and wherein the at least one flexure member defines a camming surface and the shield proximal end defines an opposing camming surface; and

axially displacing the shield into the housing causing the opposing camming surfaces to engage and release the at least one flexure member of engagement with the carrier, such that the drive spring moves the carrier from a retracted position wherein the distal end of the skin puncturing element is disposed within the shield to a puncturing position wherein the distal end is exposed from the shield to puncture the skin of the patient under the biasing force of the drive spring, and wherein the carrier is returned to a position within the housing wherein the shield encompasses the skin puncturing element under the biasing force of the retraction spring.

23. A method of actuating a medical puncturing device comprising:

providing a medical device having:

a housing comprising an actuating member extending internally therein;

a shield having a proximal end disposed in the housing and axially movable relative to the housing, the shield having at least one retaining tab;

a skin puncturing assembly disposed within the housing and comprising a movable carrier and a skin puncturing element mounted to the carrier, a distal end of the skin puncturing element adapted to puncture the skin of a patient, the at least one retaining tab engaging the carrier; and

a drive spring disposed within the housing and adapted to move the carrier in the shield;

wherein the actuating member defines a camming surface engaging an opposing camming surface on the shield proximal end; and

axially displacing the shield into the housing causing the opposing camming surfaces to engage and release the at least one retaining tab of engagement with the carrier, such that the drive spring moves the carrier from a retracted position wherein the distal end of the skin puncturing element is disposed within the shield to a puncturing position wherein the distal end is exposed from the shield to puncture the skin of the patient under the biasing force of the drive spring.

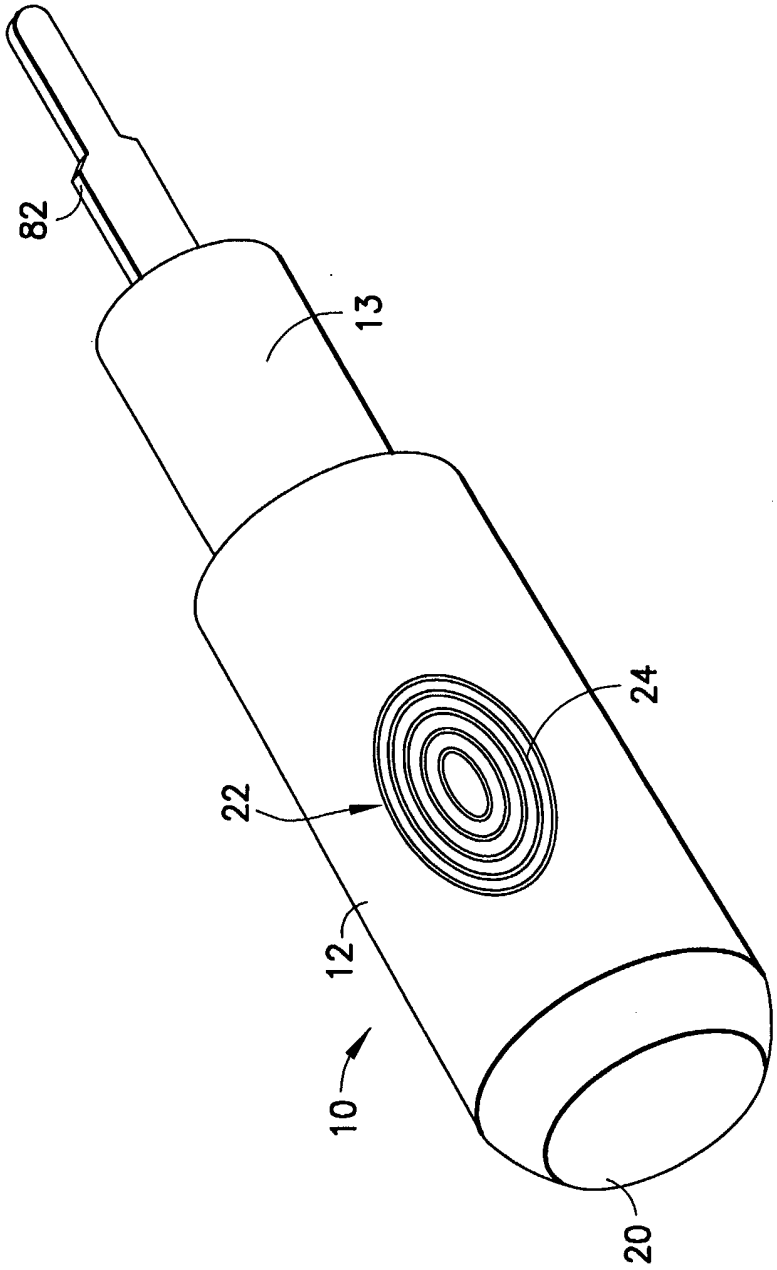

FIG.1

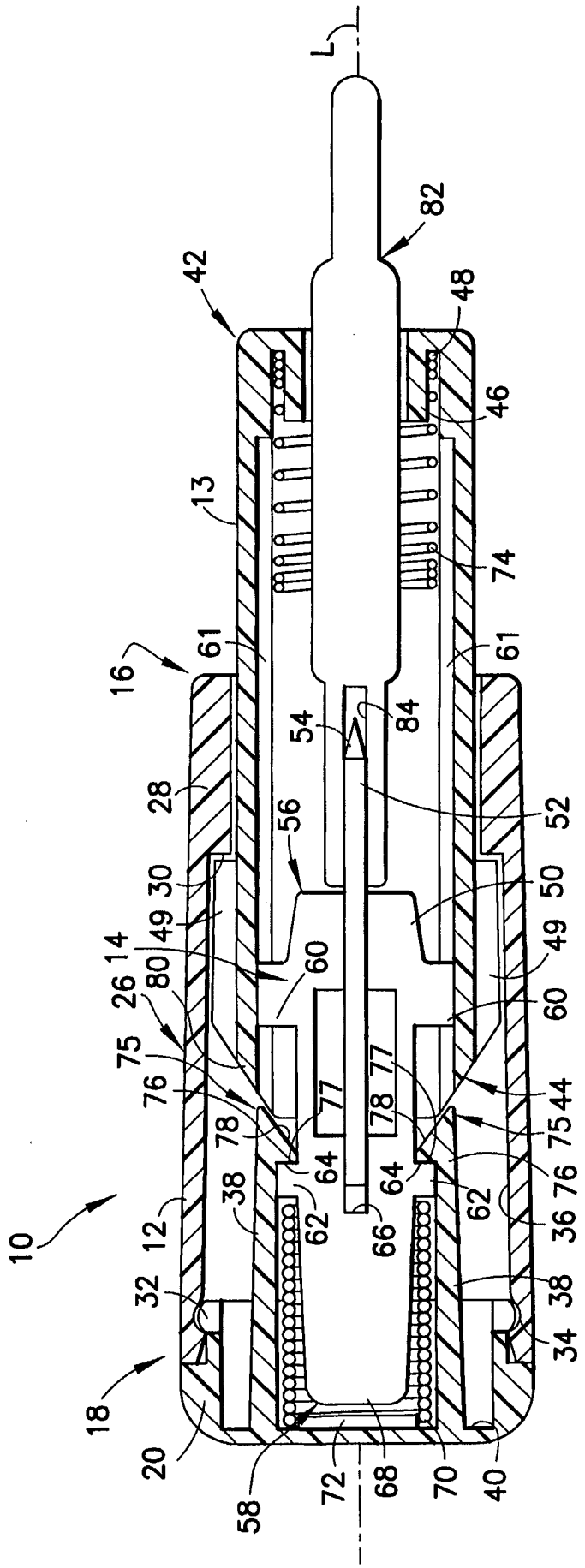
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FIG.2

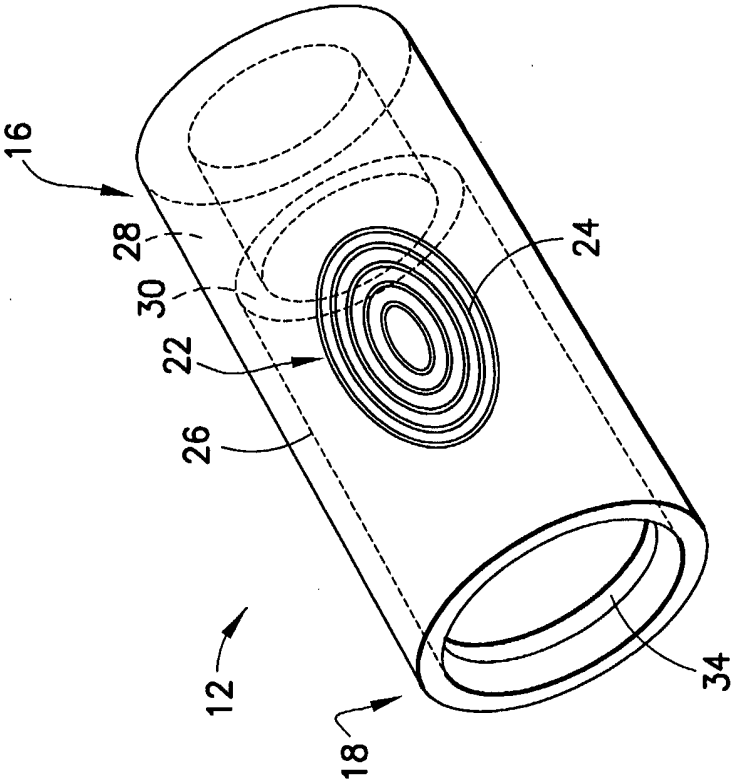

FIG.3

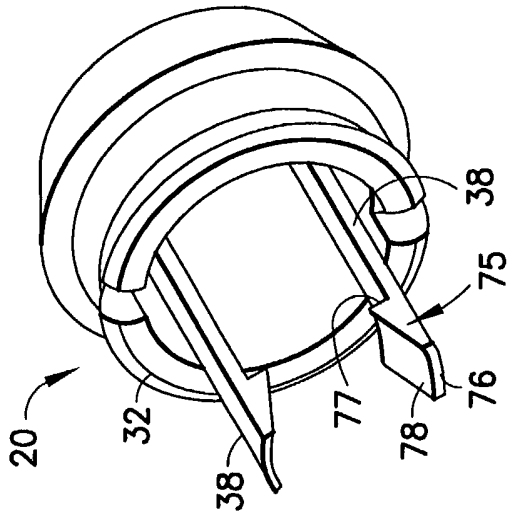

FIG.5

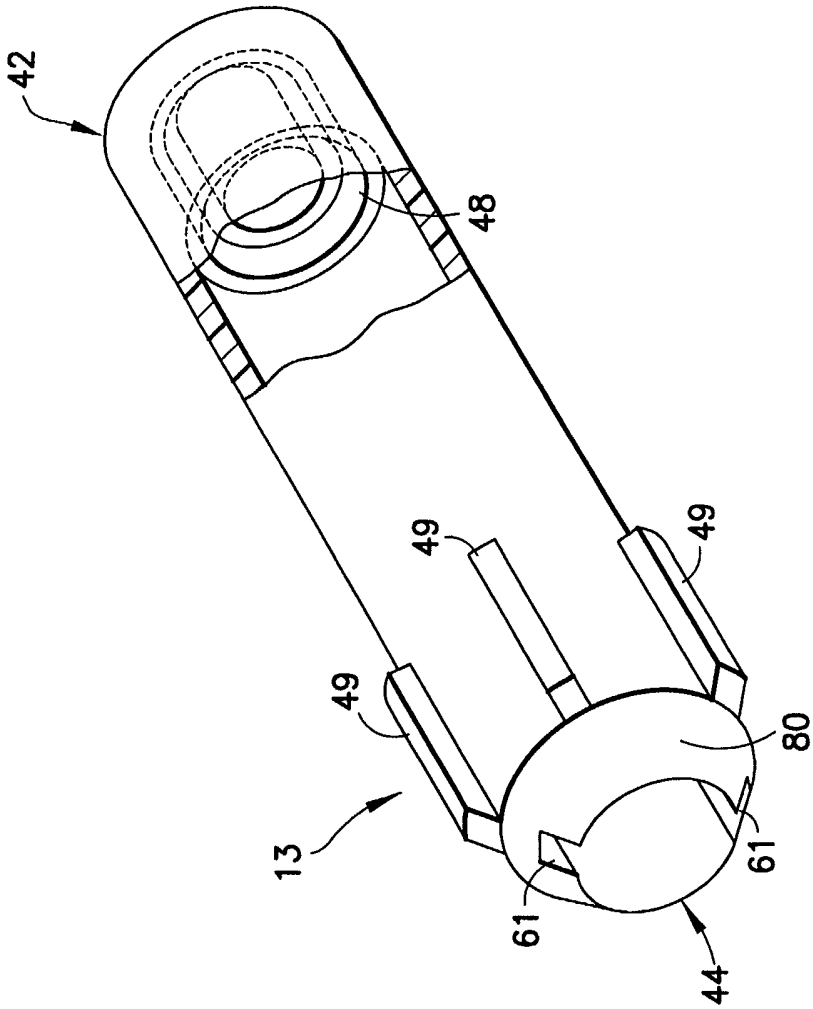

FIG.4

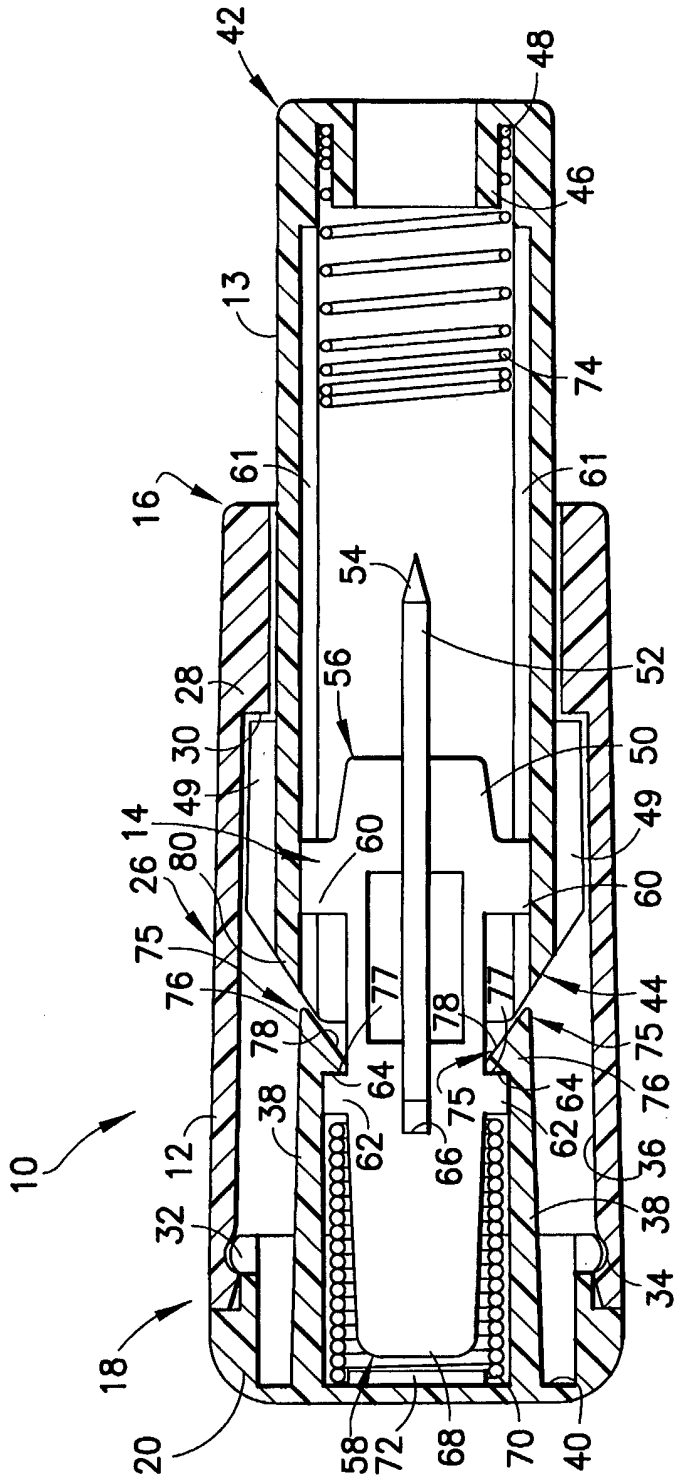
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FIG.6

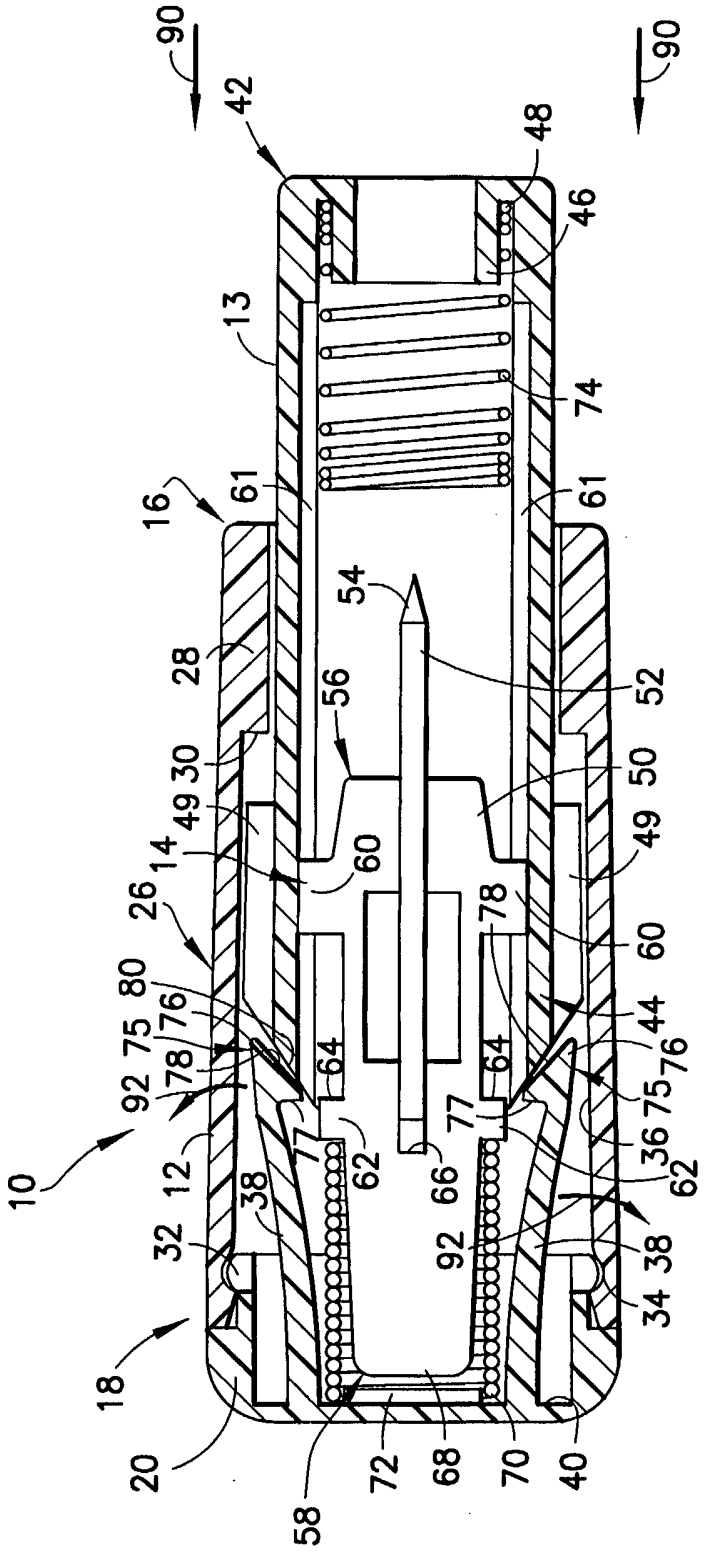
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FIG.7

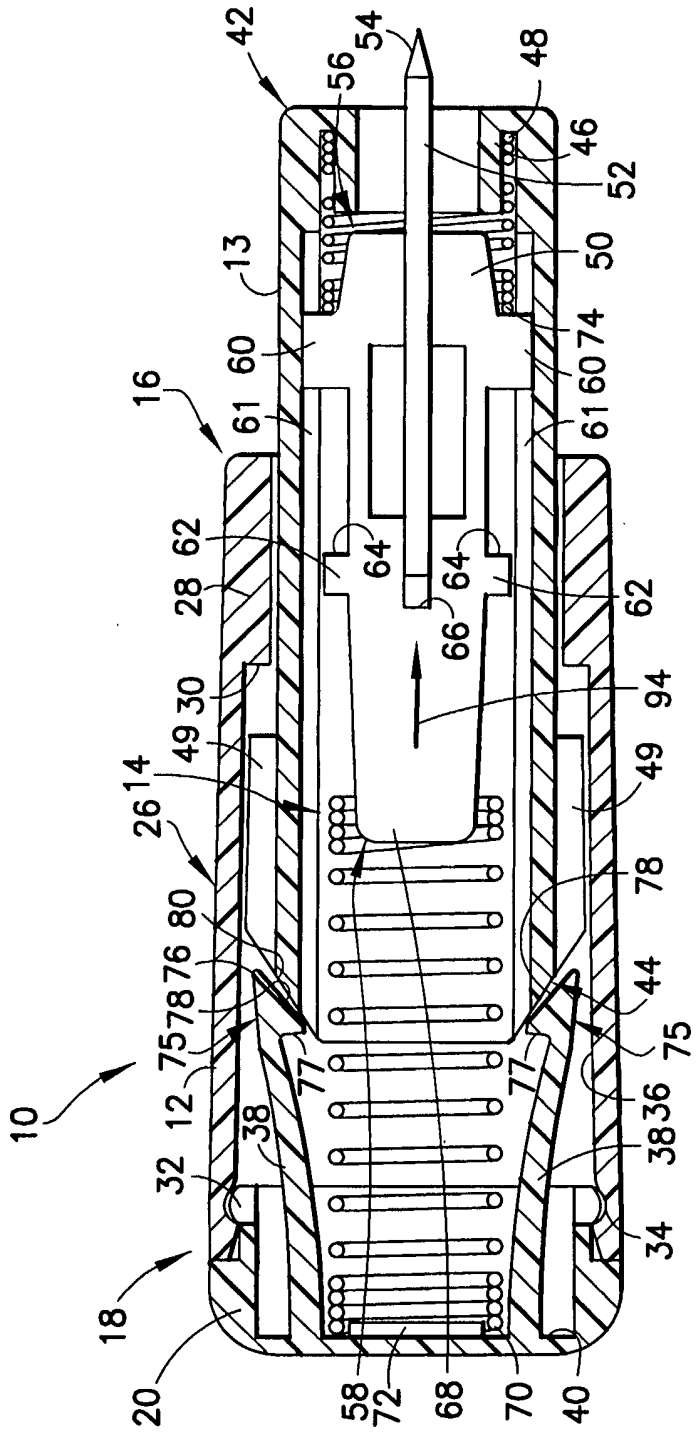
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FIG.8

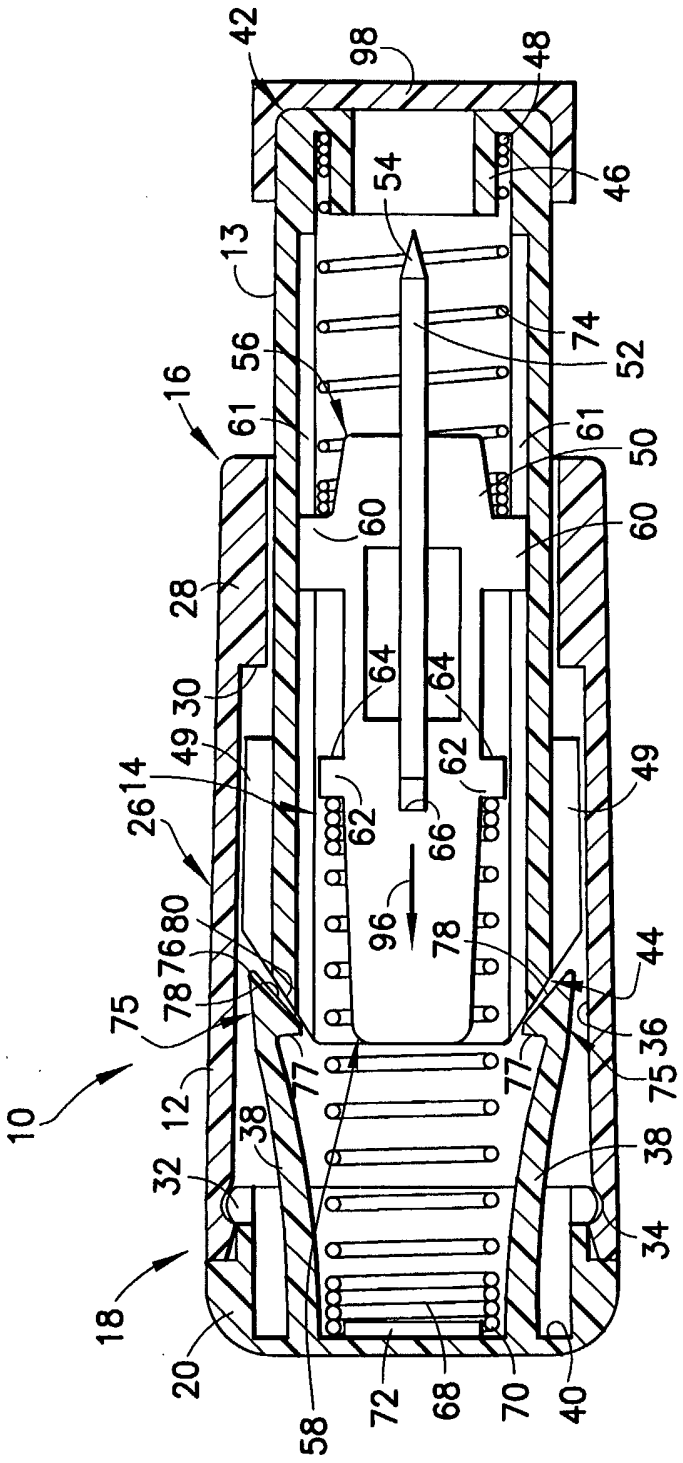
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FIG.9

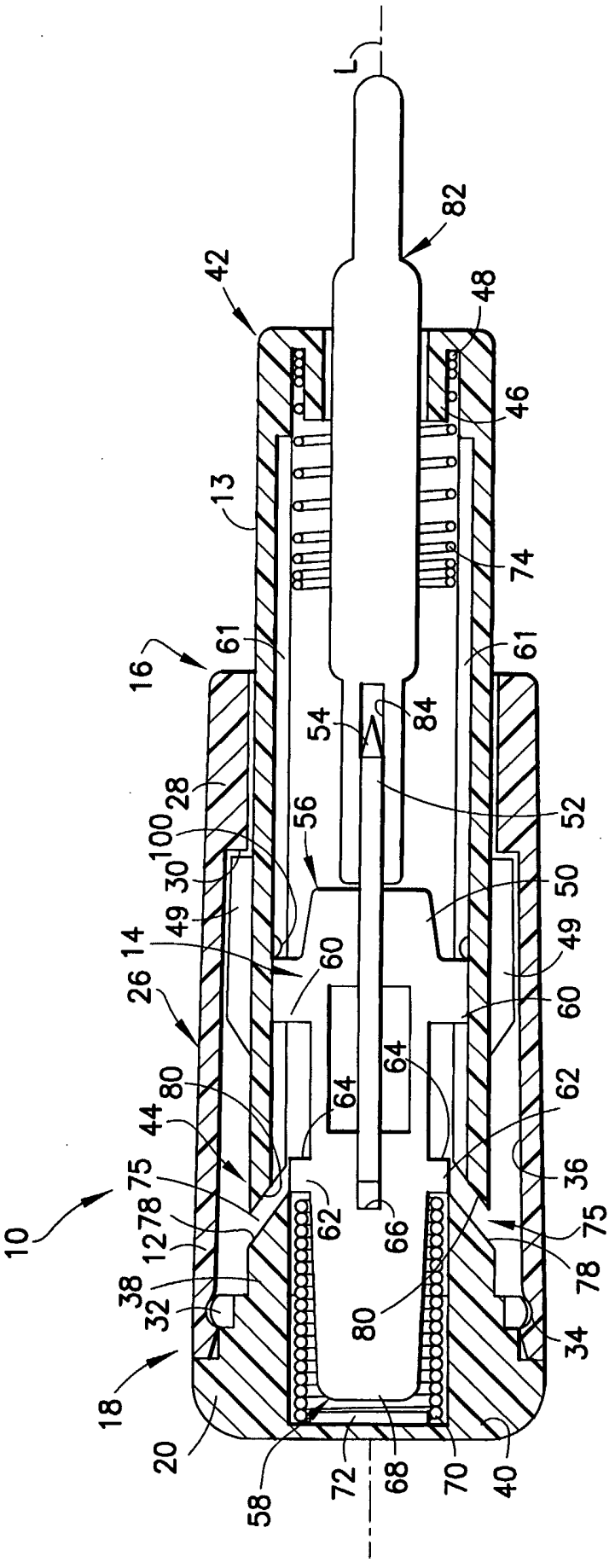
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FIG.10

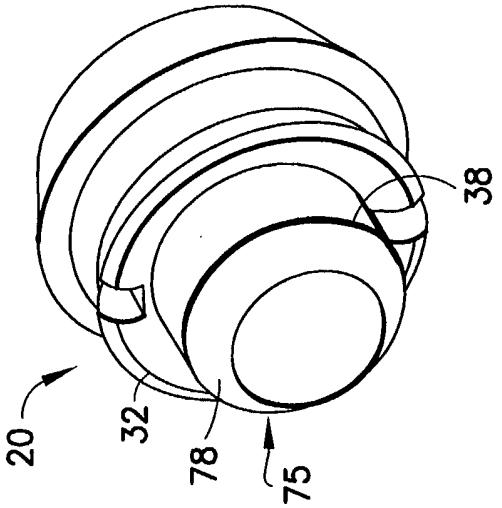

FIG.12

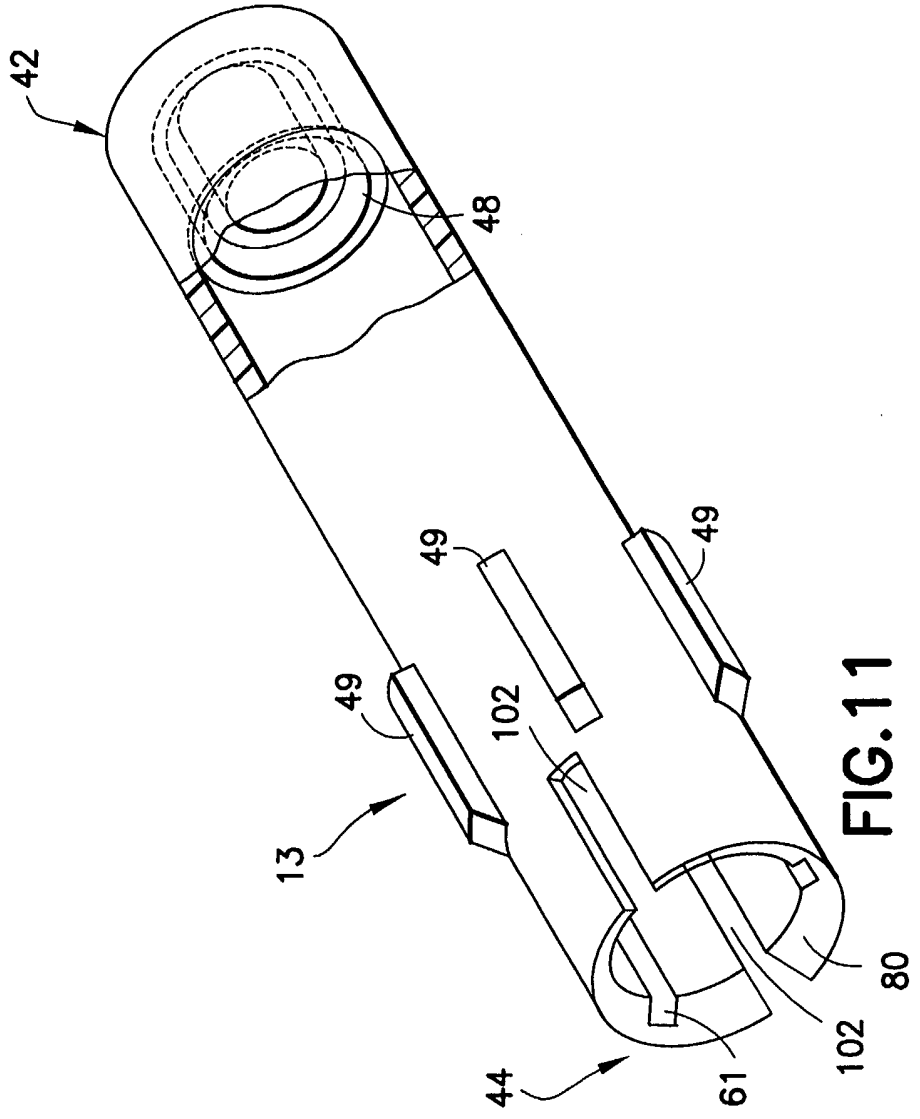

FIG.11

INTERNATIONAL SEARCH REPORT

Inte al Application No
PCT/US2005/015859

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B5/15

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

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

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4 637 403 A (GARCIA ET AL) 20 January 1987 (1987-01-20) column 6, lines 20-58; figures 4,6-9 column 7, lines 17-62 column 9, line 18 - column 10, line 55	1-7,18
X	-----	20,21
Y	US 5 540 709 A (RAMEL ET AL) 30 July 1996 (1996-07-30) column 2, line 42 - column 3, line 41; figures 1-8	1-7,18
Y	column 4, lines 24,25; figures 10,13	8,9
A	column 2, line 65 - column 3, line 2	14,15
X	-----	20,21
	-/--	

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
5 August 2005	23/08/2005

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Kronberger, R

INTERNATIONAL SEARCH REPORT

Intern al Application No
PCT/US2005/015859

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 6 248 120 B1 (WYSZOGRODZKI WOJCIECH) 19 June 2001 (2001-06-19) cited in the application column 1, line 66 - column 2, line 40; figures 1-4	1-9,12, 18,19
X Y	US 6 432 120 B1 (TEO HOCK MENG) 13 August 2002 (2002-08-13) column 3, line 17 - column 4, line 65; figures 1,3b,4d,4b,4a	10,11, 13,16,17 12,19
X	WO 03/049613 A (SHIN, BAG, SIG) 19 June 2003 (2003-06-19) page 5, line 10 - page 6, line 27; figures 1-3,4a,4b page 7, line 1 - page 8, line 30	10,11, 13-16

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2005/015859

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 22,23
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Inter al Application No
PCT/US2005/015859

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 4637403 A	20-01-1987	US 4627445 A	09-12-1986
		AT 86843 T	15-04-1993
		AU 5699086 A	05-11-1986
		DE 3687994 D1	22-04-1993
		DK 589486 A	08-12-1986
		EP 0199484 A2	29-10-1986
		JP 61286738 A	17-12-1986
		WO 8605966 A1	23-10-1986
		US 5279294 A	18-01-1994
		US 4787398 A	29-11-1988
		CA 1277896 C	18-12-1990
		CA 1308006 C	29-09-1992
US 5540709 A	30-07-1996	US 5366470 A	22-11-1994
US 6248120 B1	19-06-2001	NONE	
US 6432120 B1	13-08-2002	SG 85117 A1	19-12-2001
		AU 4637800 A	09-01-2001
		EP 1204372 A2	15-05-2002
		JP 2003502088 T	21-01-2003
		WO 0078203 A2	28-12-2000
WO 03049613 A	19-06-2003	KR 2003042393 A	28-05-2003
		WO 03049613 A1	19-06-2003