EXHIBIT A

US006524276B1

(12) **United States Patent**
Halseth et al.

(10) **Patent No.: US 6,524,276 B1**
(45) **Date of Patent: Feb. 25, 2003**

(54) **FLUID COLLECTION DEVICE HAVING TILTING RETRACTABLE NEEDLE**

(75) Inventors: **Thor R. Halseth**, Simi Valley, CA (US); **Michael J. Botich**, Oxnard, CA (US); **Robert T. McWethy**, Ventura, CA (US)

(73) Assignee: **MDC Investment Holdings, Inc.**, Wilmington, DE (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/588,151**

(22) Filed: **Jun. 5, 2000**

(51) **Int. Cl.**[7] **A61M 5/00**
(52) **U.S. Cl.** **604/110**
(58) **Field of Search** 604/110, 199, 604/86, 162, 164.08, 171, 201, 264, 268, 272; 128/919

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,770,655	A		9/1988	Haber
4,846,808	A		7/1989	Haber
4,883,466	A		11/1989	Glazier
4,908,022	A		3/1990	Haber
4,909,794	A		3/1990	Haber
4,915,702	A		4/1990	Haber
4,932,940	A		6/1990	Walker
4,986,813	A		1/1991	Blake, III
5,019,044	A	*	5/1991	Tsao 604/110
5,085,640	A		2/1992	Gibbs
5,122,118	A		6/1992	Haber
5,181,524	A		1/1993	Wanderer
5,211,629	A	*	5/1993	Pressly et al. 604/110
5,273,540	A		12/1993	Luther
5,336,198	A		8/1994	Silver
5,346,480	A		9/1994	Hess
5,382,235	A		1/1995	Suk
5,393,301	A		2/1995	Goldberg
5,407,436	A	*	4/1995	Toft et al. 604/195
5,433,703	A		7/1995	Utterberg
5,456,668	A		10/1995	Ogle, II
5,533,975	A		7/1996	Lu
5,752,936	A	*	5/1998	Chen 604/110
5,800,403	A	*	9/1998	Pressly, Sr. et al. 604/195
5,993,419	A	*	11/1999	Lo et al. 604/110
6,074,370	A	*	6/2000	Pressly, Sr. et al. 604/195
6,090,077	A	*	7/2000	Shaw 604/195
6,096,005	A	*	8/2000	Botich et al. 604/110
6,099,500	A	*	8/2000	Dysarz 604/110
6,117,113	A	*	9/2000	Novacek et al. 604/195
6,241,707	B1	*	6/2001	Dysarz 604/110

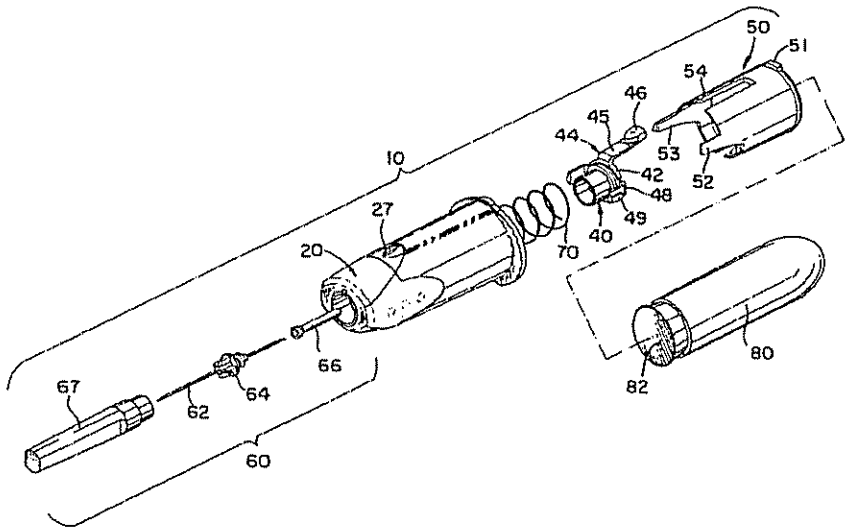
* cited by examiner

Primary Examiner—Brian L. Casler
Assistant Examiner—Kevin C. Sirmons
(74) *Attorney, Agent, or Firm*—Stephen H. Eland; Dann, Dorfman, Herrell and Skillman

(57) **ABSTRACT**

A medical device is provided for collecting fluid samples from a patient, such as blood samples. The device includes a needle having a forward sharpened tip that is retracted into the housing of the device after use to prevent exposure to the contaminated needle. The rearward end of the housing is open, forming a socket for receiving a fluid container, such as a vacuum tube, that will receive the fluid sample. A needle retainer releasably retains the needle in the extended position against the rearward bias of a biasing element. After use, the medical professional retracts the needle by pressing an actuation button, allowing the biasing element to displace the needle rearwardly. A guide track guides the needle during retraction, tilting the needle off-axis.

32 Claims, 4 Drawing Sheets



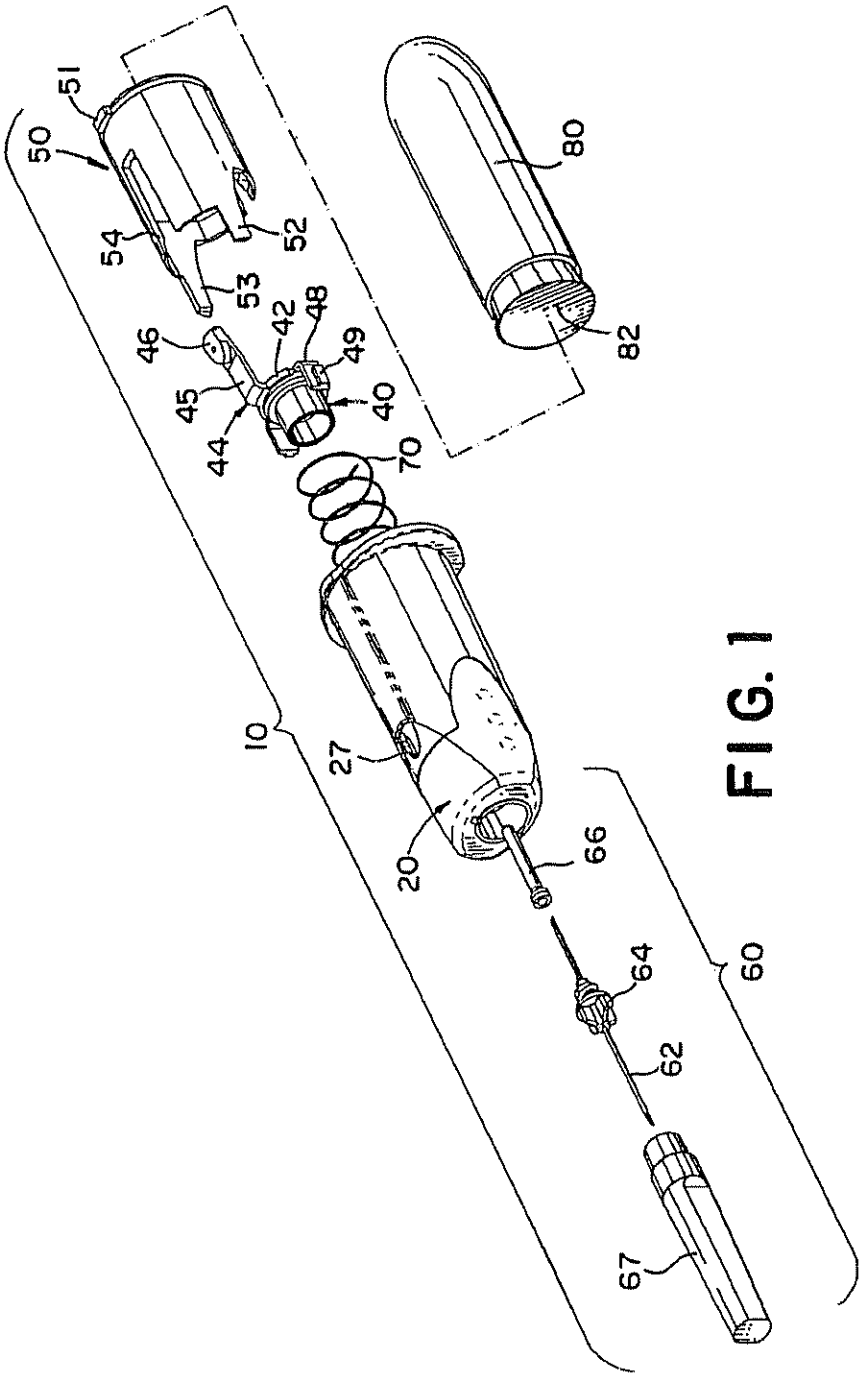


FIG. 1

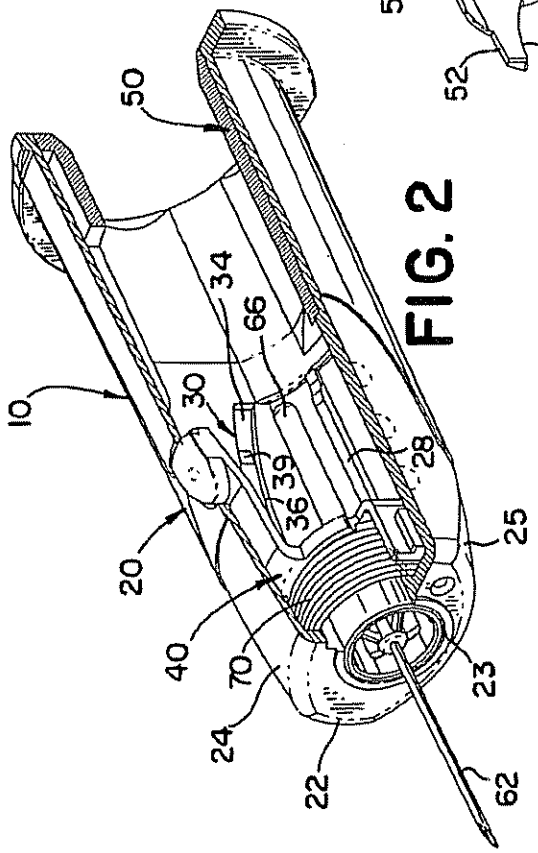


FIG. 2

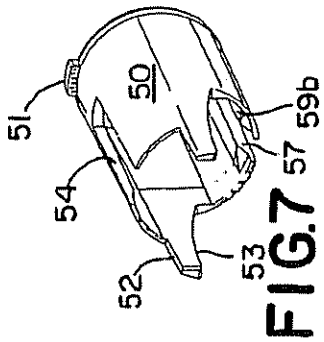


FIG.7

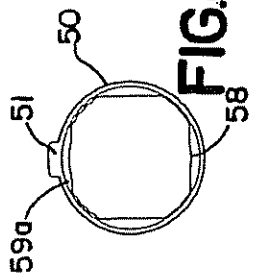


FIG.8

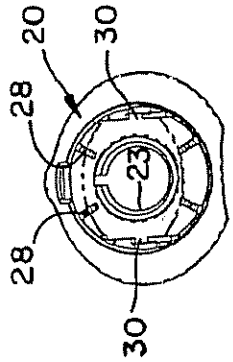


FIG. 6

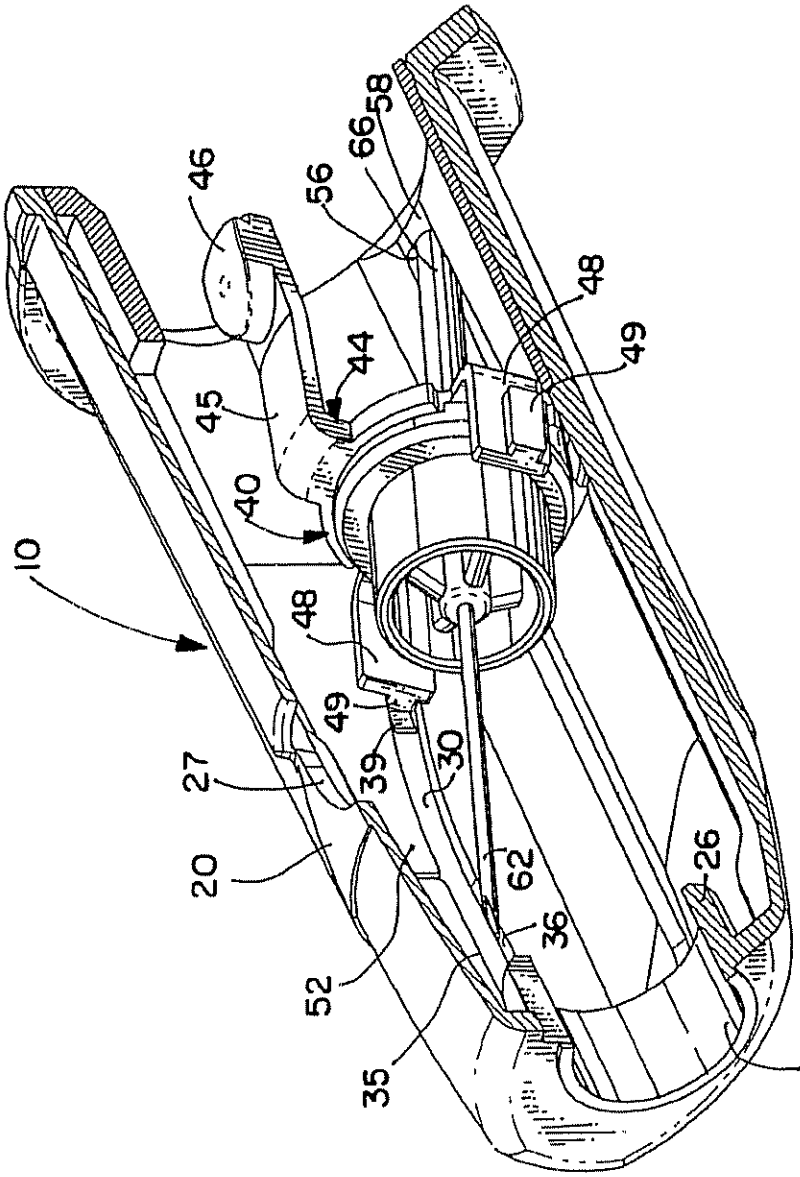


FIG. 3

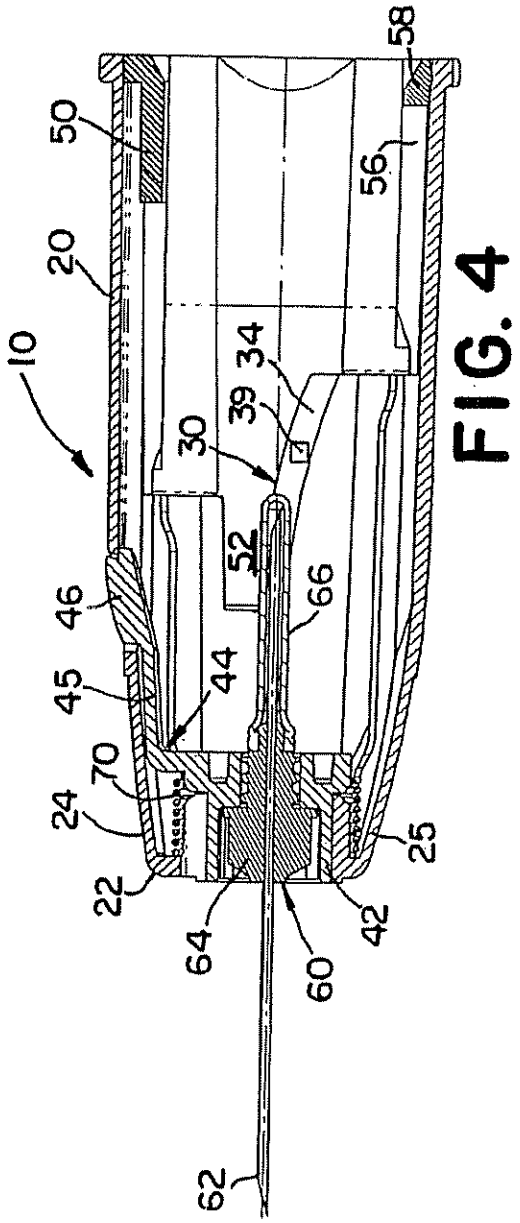

58
50
56
20
10
34
39
30
52
66
46
45
44
70
24
22
64
60
42
25
62

FIG. 4

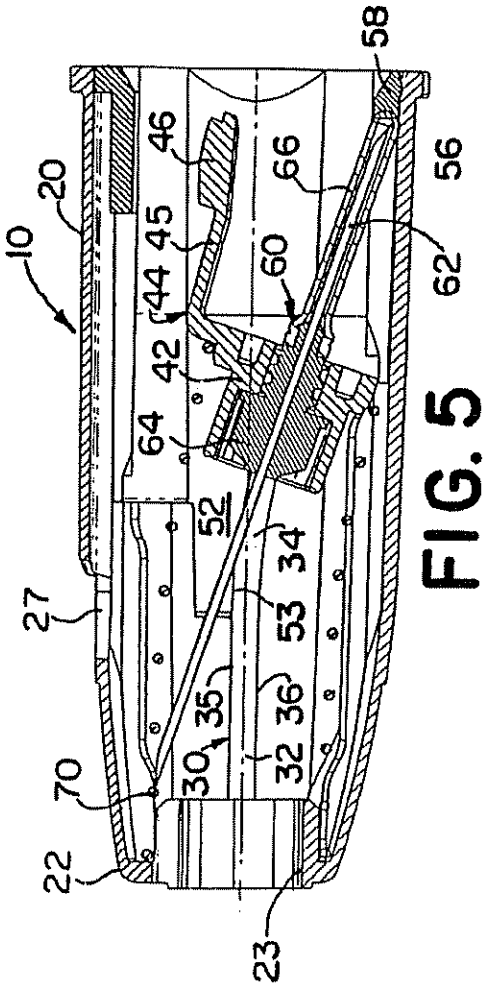

58
46
66
56
20
10
45
44
60
62
42
64
52
34
27
53
35
36
32
30
70
22
23

FIG. 5

FLUID COLLECTION DEVICE HAVING TILTING RETRACTABLE NEEDLE

FIELD OF THE INVENTION

The present invention relates to fluid collection devices for sampling fluid from a patient. More specifically, the invention relates to such a device having a retractable needle feature for rendering the device non-reusable and safely disposable.

BACKGROUND OF THE INVENTION

Various types of medical devices employ a needle for piercing the skin of a patient for diagnostic or therapeutic purposes. One such device is a phlebotomy or blood collection device that includes a needle for piercing a blood vessel of the patient to allow blood to be sampled from the patient. When the needle is inserted into the blood vessel of the patient, blood is withdrawn through the needle into a vacuum collection tube. Handling of such needle-bearing medical devices after the needle is withdrawn from the patient can result in transmission of various pathogens, most notably human immune virus (HIV), to uninfected medical personnel, due to an inadvertent needle stick.

Since the mid-1980s, concern over the risk of accidental needle stick injuries has spawned a number of design approaches for safety needle devices. Such devices can be broadly categorized as sliding sheath needle devices, wherein a physical barrier is positioned about the needle tip after use, and as needle-retraction devices, wherein the tip of the needle is retracted into the device after use.

The known devices suffer from one of several problems, including complicated structures that increase the cost of manufacturing the device. A safety needle product may be safe, but if it is too expensive, it will not be accepted, and the benefits of the safety product will never be recognized by the medical community. In addition, many devices require awkward or cumbersome actions to cause the needle to retract. The more complicated it is to retract a needle, the less likely it is that the medical professional will take the time to retract the needle, particularly in emergency situations.

In addition, in the field of phlebotomy, many of the known devices do not adequately protect against inadvertent contact with the non-patient tip of the needle. Since a person's finger is generally smaller than the rearward opening of a phlebotomy device, the rearward end of the needle remains a safety concern after it has been contaminated with a patient's blood. The known medical devices do not adequately address the protection needed to efficiently shield both the forward and rearward ends of the needle.

SUMMARY OF THE INVENTION

In light of the foregoing, the present invention provides a safety medical device having a retractable needle. The present invention is particularly suited for operation in connection with a fluid container such as a vacuum tube used for phlebotomy. The device includes a needle having a sharpened tip for piercing a patient. Preferably, the needle is double-ended having a rearward sharpened tip for piercing a seal on a fluid container. After use, the needle is retracted into the housing of the device so that the forward end of the needle is enclosed to prevent inadvertent contact with the contaminated needle.

The invention includes a biasing element such as a spring that biases the needle rearwardly toward the retracted position in which the needle is enclosed within the housing. The needle retainer releasably retains the needle against the bias of the spring so that the forward tip of the needle is exposed for use. After use, the medical professional actuates retraction to release the needle so that the spring displaces the needle rearwardly into the retracted position.

Another object of the invention is to provide a guide for guiding the needle when the needle is displaced between the projecting position and the retracted position. The guide includes at least one track and at least one guide tab connected with the needle, and projecting into operative engagement with the track. The track has an axial portion extending substantially parallel to the axis of the housing and a transverse portion extending transverse the axis of the barrel so that during retraction the needle is tilted so that the needle is disposed transverse the axis of the housing in the retracted position.

Yet another object of the invention is to provide a pocket for receiving and protecting the rearward sharpened tip of the needle when the needle is disposed in the retracted position. The pocket may be formed in a cylindrical insert that lines the housing. Preferably, the insert further includes a wing projecting forwardly and intersecting the guide. The wing has a lower edge configured in the shape of the transverse portion of the track, wherein the lower edge of the wing forms a sidewall of the transverse portion of the track.

BRIEF DESCRIPTION OF THE DRAWINGS

The foregoing summary as well as the detailed description below will be better understood when read in conjunction with the drawings, in which:

FIG. **1** is an exploded perspective view of a medical device having a retractable needle manifesting aspects of the present invention;

FIG. **2** is a perspective view of the medical device illustrated in FIG. **1**, partially in section;

FIG. **3** is a perspective view of the medical device illustrated in FIG. **1**, partially in section, showing the needle in a retracted position;

FIG. **4** is a side cross-sectional view of the medical device illustrated in FIG. **1**;

FIG. **5** is a side cross-sectional view of the medical device illustrated in FIG **1**, showing the needle in a retracted position;

FIG. **6** is a right-side view of the barrel of the medical device illustrated in FIG. **1**;

FIG. **7** is a perspective view of an insert forming part of the medical device illustrated in FIG. **1**; and

FIG. **8** is a right-side view of the insert illustrated in FIG. **7**.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to the drawings in general, and to FIG. **1** specifically, a needle-bearing medical device is designated generally **10**. The device **10** is operable in connection with a fluid container **80**, such as a fluid sampling container for use in drawing blood samples. The device **10** includes a double ended needle **62**. The forward end of the needle is inserted into the patient and the rearward end of the needle pierces a seal **82** on the container **80**. After use, the container is removed, and if desired, further containers **80** are used to take further samples while the forward end of the needle remains in the patient. After the last container **80** is removed,

the needle is retracted into the device **10** to protect against inadvertent contact with the contaminated needle.

As shown in FIG. **1**, the device includes five elements or subassemblies: a needle assembly **60**, a substantially hollow barrel **20**, a spring **70**, a needle holder **40**, and an insert **50**. Referring to FIG. **4**, the needle **62** projects forwardly from the forward end of the barrel. The spring **70** biases the needle rearwardly, while the needle holder **40** releasably retains the needle **62** against the rearward bias of the spring **70**. The needle holder **40** includes a needle retainer **44** having a pushbutton **46** operable by the medical professional using the device **10**. After use, the medical professional depresses the button **46** to retract the needle. After the button is pressed, the spring displaces the needle holder **40** and needle **62** rearwardly. As the needle is retracted, a guide track **30** formed in the interior wall of the barrel **20** guides the needle so that the needle tilts off-axis, as shown in FIG. **5**.

The details of the barrel **20** will now be described more fully with reference to FIGS **1**, **2**, **4** and **6**. The barrel is a hollow, generally cylindrical element having an open rearward end for receiving the fluid container **80**. The forward end tapers radially inwardly forming a nose **22** having an opening **23** for receiving the needle assembly **60**. The nose **22** can be formed so that it tapers inwardly around the entire circumference of the barrel. However, as shown in FIG. **1**, the sides of the nose generally do not taper radially inwardly. Instead, only the top and bottom surfaces of the barrel taper inwardly forming a flattened wedge-shaped nose **22**.

In this way, the nose **22** has a top face **24** and a bottom face **25**. The two faces **24**, **25** may be curved circumferentially as shown in FIG. **1**, and, preferably the radius of curvature of the top and bottom faces is significantly larger than the radius of curvature of the side portions of the nose. In addition, preferably, the bottom face **25** tapers inwardly at a greater angle relative to the central barrel axis than the top face **25**, as can be seen in FIG. **4**.

As shown in FIG. **4**, an annular support collar **26** intersects the nose opening **23** forming a reduced diameter cylindrical bore within the nose **22**. The support collar **26** aligns the needle assembly **60** with the needle holder **40** and supports the needle assembly and the needle holder.

A plurality of circumferentially spaced axially elongated ribs **28** are provided for aligning the fluid container **80** when it is inserted into the device to ensure that the container is substantially centered within the housing so that the rearward end of the needle pierces the seal of the container. The ribs **28** are integrally formed with the barrel **20** so that the ribs protrude radially inwardly from the inner surface of the barrel.

The interior wall of the barrel is relieved to form a recess for receiving the insert **50**. More specifically, the barrel is relieved in a shape to cooperate with the shape and thickness of the insert **50** to form a smooth wall transition between the interior of the insert **50** and the interior of the barrel **20** as shown in FIGS. **2** and **4**. An alignment key **51** shown in FIG. **1**, integrally formed at the rearward end of the insert **50** cooperates with a recess formed at the rearward end of the barrel to circumferentially align the insert relative to the barrel.

The barrel **20** further includes a pair of guide tracks **30** formed in its inner wall, which guide the needle assembly **60** and needle holder **40** during retraction. Preferably, the guide tracks **30** are disposed in opposing relation and are substantially a mirror of one another about the central axis of the device **10**. Each guide track **30** comprises a groove support channel formed in the barrel wall. However, if desired, the guide tracks can be slots through the wall instead of grooves. In addition, although the device is described as having a pair of guide tracks, the device can be configured to use only a single guide track formed in the barrel.

The guide track **30** includes two portions, an axial portion **32** extending substantially parallel to the central axis of the device, and a transverse portion **34** intersecting the axial portion and extending transverse the central axis of the device. The groove of the guide track **30** has an upper wall **35** and a lower wall **36**. The groove can be formed so that the upper and lower walls **35**, **36** extend along the entire length of the axial portion **32** and the transverse portion **34**. However, as described further below, the barrel **20** can be molded more efficiently if one of the track walls **35**, **36** does not extend along the entire length of the track.

Specifically, in the present instance, the upper wall **35** of the guide track **30** extends along the axial portion **32** but does not extend along the entire length of the transverse portion **34**. The height of the upper wall **35** reduces along the length of the transverse portion **34** to a point at which there is no longer an upper wall **35** of the groove formed in the barrel. In other words, the upper wall **35** feathers out into a recess formed in the barrel for receiving the insert **50**, which has a pair of wings **52**. These wings **52** form the upper wall of the groove along the transverse portion **34** as discussed further below.

Referring to FIG. **7**, the insert **50** is a hollow, generally cylindrical element. The insert **50** is separately formed from the barrel **20** and then preferably fixedly connected with the barrel. The insert **50** may be connected to the barrel in a variety of ways, such as adhesive or ultrasonic welding. However, in the present instance, the insert and barrel are snap fit together. Specifically, a circumferential rib projecting radially outwardly from the outer surface or the rearward end of the insert engages an annular groove in the interior wall of the rearward end of the barrel.

A pair of axially elongated slots **54**, **57** extend rearwardly from the forward end of the insert, terminating adjacent the rearward end of the insert. The first slot **54** is located on the upper half of the insert, and provides clearance for the needle holder **40** as the needle is retracted, so that the insert does not interfere with the needle holder, which would impede retraction as can be seen in FIGS. **4**, **5** and **7**. The second slot **57** is located on the lower half of the insert **50**, opposing the first slot **54**. The rear wall **58** at the terminal end of the lower slot **57**, together with the walls of the lower slot, form a pocket **56** for protecting the rearward end of the needle after the needle is retracted, as shown in FIGS. **3**, **5**.

The interior of the insert is configured to form a socket for receiving the fluid container **80**. Specifically, the interior of the insert **50** is configured to locate and center the fluid container to minimize lateral movement of the fluid container within the device **10**. As shown in FIGS. **7–8**, the interior sidewalls of the insert have substantially planer portions that projects inwardly from the generally curved interior surface of the insert. The upper and lower interior walls have axially elongated ribs **59***a*, **59***b* that straddle the upper and lower slots **54**, **57** projecting radially inwardly from the generally curved interior surface of the insert.

A pair of opposing wings **52** project forwardly from the forward end of the body of the insert. The wings are substantially parallel to one another and the central axis of the insert, opposing one another. The wings **52** preferably have a thickness that is substantially similar to the depth of the guide track **30** groove. The lower edge **53** of each wing **52** forms a curve having a shape or curvature similar to the transverse portion **34** of the guide track **30**.

As discussed previously, the groove that forms the rearward end of the guide track formed in the barrel opens up because the upper wall of the transverse portion of the groove feathers out into a recess in the barrel so that there is no upper wall. Instead, the lower edge **53** of the wings **52** form the upper wall **35** of the guide track **30** along the transverse portion **34** of the guide track as follows.

During assembly, the insert **50** is aligned with and connected to the barrel **20** so that the lower edge **53** of each arms is circumferentially spaced apart from the lower wall **36** of the guide track along the transverse portion **34**. The insert is located so that the configuration of the lower edge **53** of each arm **52** is substantially parallel to the lower wall **36** of the transverse portion **34** of the guide track groove. In this way, the transverse portion **34** of the guide track is formed by the lower edge **53** of each wing arm **52** and the open groove formed in the interior surface of the barrel **20**.

Referring now to FIGS. **1** and **4**, the details of the needle holder **40** will be described in greater detail. The needle holder **40** is configured to cooperate with the needle assembly **60**. The needle holder includes a generally cylindrical central hub **42**, a needle retainer **44** projecting radially outwardly from the hub and a pair of opposing guide arms **48** projecting outwardly from the hub. The hub **42** is hollow, having a bore for receiving the needle assembly **60**.

The guide arms **48** cooperate with the guide track **30** to guide the needle holder during retraction. Specifically, the guide arms project radially outwardly from the hub **42** opposing one another. The terminal end of each guide arm **48** forms a tab **49** configured to cooperate with the channel of the guide track **30**. The guide tab **49** projects into the groove of the guide track **30** so that during retraction the guide arm **48** and the attached hub **42** follow the track. The guide arms **48** are radially deformable, and may be formed so that the guide arms are biased radially outwardly to ensure that the tabs **49** engage the guide tracks **30**.

As shown in FIGS. **4**, **5**, the needle holder **40** is operable between an extended position and a retracted position. In the extended position, the needle holder hub **42** is located within and supported by the support collar **26** located inside the forward end of the barrel. The support collar centers the needle holder and the attached needle assembly **60** so that the needle assembly is substantially centered in the barrel and the needle is substantially parallel to the central axis of the barrel. In the retracted position, the needle holder **40** and attached needle assembly **60** are displaced rearwardly into the barrel **20**.

The spring **70** is a coil spring circumscribing the needle **62**. The forward end of the spring bears against the forward end of the barrel **20** and the rearward end of the spring bears against the needle holder **40**.

The needle retainer **44** attached to the hub **42** releasably retains the needle against the rearward bias of the spring **70**. The needle retainer comprises an elongated radially deformable arm **45** and a button or latch **46** integrally formed at the terminal end of the arm. Preferably, the needle retainer is molded so that the arm is biased radially outwardly to bias the button **46** into engagement with an aperture **27** in the barrel **20**. The button **46** operates as a latch engaging the rim of the aperture **27** in the barrel. The button **46** projects into the aperture so that it is exposed for manual actuation by the medical professional.

The needle may be fixedly attached to the needle holder **40** during manufacture. However, preferably the needle is configured as an element of a separate needle assembly **60** so that it can be attached to the needle holder either by the manufacturer or by the medical professional prior to use. In the present instance, the needle assembly includes a double ended needle **62**, a hub **64**, a forward needle cover **68** and a pierceable needle cover **67** that covers the rearward end of the needle. The needle hub **64** is configured to cooperate with the needle holder **40** to attach the needle assembly **60** to the needle holder. For instance, the needle hub **64** may include external threads that the threadedly engage internal threads in the bore of the needle holder **40**. However, in the present instance, the needle hub **64** and the needle holder **40** are connected by an interference or friction fit.

The needle hub **64** includes a bore through which the needle **62** extends, and the needle hub is bonded to the needle by adhesive. The rearward end of the needle hub **64** forms a barb for attaching the needle cover **66** to the needle hub. The rear needle cover **66** is formed of a pierceable resealable elastomeric material. The forward needle cover **67** is formed of a hard plastic.

As shown in FIG. **4**, prior to use the rear needle cover **67** encloses the rearward end of the needle. During use, a fluid container **80** is inserted into the device so that the rearward end of the needle pierces a seal **82** on the fluid container. As the fluid container is mounted on the needle, the fluid container seal **82** compresses the needle seal **66** along the length of the needle. As the fluid container compresses the needle seal, the needle pierces the rear needle cover and then pierces the fluid container seal. When the fluid container is removed, the rear needle cover resiliently rebounds to re-extend over the needle to form a fluid-tight seal over the rearward end of the needle. This prevents fluid from leaking out the rearward end of the needle when a fluid container is not engaged.

Configured as described above, the device **10** operates as follows. The medical professional connects the needle assembly to the needle holder **40** by attaching the needle hub **64** to the needle holder hub **42**. After the needle assembly **60** is attached, the forward needle cover **67** is removed. This is the configuration of the device **10** prior to use illustrated in FIG. **4**.

The medical professional then inserts the needle into a patient's vein and then inserts a vacuum tube **80** into the rearward end of the barrel and displaces the vacuum tube forwardly until the needle pierces the seal **82** of the vacuum tube and the forward end of the tube is seated against the needle holder hub **42**. Blood flows from the patient into the vacuum tube **80**.

Frequently multiple samples are taken. In such situations, the first vacuum tube is removed from the device. After removing the vacuum tube, the needle cover **66** extends over the rearward end of the needle to seal the needle so that blood does not continue to flow from the patient through the needle and leak out the back end of the needle while there is no vacuum tube mounted in the device. Further samples can be taken in a plurality of vacuum tubes in a manner similar to that as described above, while the needle remains in the patient.

After the final sample is taken, the medical professional removes the last vacuum tube. The used needle is contaminated with the patient's blood so it should be shielded to prevent an accidental needle stick. Accordingly, the medical professional actuates retraction to shield the needle.

Specifically, the medical professional presses the button **46** inwardly, so that the button disengages the locking aperture **27** in the barrel. As the button **46** is pressed, the needle retainer arm **45** deforms radially inwardly. Once the button disengages the locking aperture, the spring **70** displaces the needle rearwardly.

As the spring retracts the needle, the needle holder **40** follows the guide track **30**. During the first part of retraction, the needle is displaced rearwardly parallel to the central axis of the barrel. The upper slot **54** in the insert **50** and an axial groove in the top of the barrel **20** provide clearance for the needle retainer arm **45** and button **46** as they are retracted rearwardly. After the guide arms **48** of the needle holder engages the transverse portion **34** of the guide track **30**, continued rearward displacement displaces the needle rearwardly, while simultaneously tilting the needle away from the central axis of the barrel.

As shown in FIG. **5**, preferably the diameter of the spring **70** is sufficiently large so that as the needle tilts, the forward tip of the needle stays within the interior of the spring so that the needle does not engage the spring, which could impede retraction. For this reason, the needle is laterally offset from the centerline of the spring. As shown in FIG. **4**, in the extended position, the needle assembly **60** is closer to the bottom of the spring than the top of the spring. In this way, a needle can tilt through a greater angle for a given diameter spring without interfering with the spring.

At the end of retraction, the rearward edge of the guide tabs **49** engage a shoulder on the insert that forms the rear wall of the guide tracks **30**. The end wall operates as a stop limiting rearward displacement of the needle assembly **60**.

Since both ends of the needle are sharpened, it is desirable to protect both ends of the needle against inadvertent contact. In addition, since the rear opening of the barrel is larger than an average person's finger, simply retracting the needle rearwardly may not adequately protect against the risk of contacting the rearward end of the needle. Accordingly, preferably, the needle is tilted off axis, as described above. In addition, preferably, the rear tip of the retracted needle is protected as discussed further below.

As described previously, a pocket is formed at the rearward end of the barrel. The pocket **56** is formed by the insert, which has a lower slot **57** terminating in an end wall **58**. The transverse portion **34** of the guide tracks are aligned with the slot and the pocket **56** Accordingly, rearward displacement of the needle displaces the rearward tip of the needle into the pocket so that the pocket **56** shields the rear tip of the needle. Specifically, the rear needle tip is displaced into the slot **54** and behind the end wall **58**, which prevent inadvertent contact with the contaminated needle. The device **10** can then be safely discarded.

Since the needle is tilted off-axis, the needle cannot be readily re-extended. However, it is desirable to include a lock or stop for impeding forward displacement of the needle after retraction to prevent re-extension of the contaminated needle.

Accordingly, the device includes a stop **39** disposed in at least one, and preferably both of the guide tracks **30** adjacent the rearward end of each guide track. The forward face of each stop **39** is tapered forming a ramp. The rearward face of each stop forms a shoulder that is substantially perpendicular to the guide track. As the needle is retracted, the guide tabs **49** ride in the guide track. The guide tabs are mounted on guide arms, which are flexible. Therefore, near the end of retraction, the guide tabs ride up the tapered face of the corresponding stop **39**. As the guide tabs ride up the ramps, the arms **48** deflect radially inwardly After the guide tabs ride over the stops, the guide tabs snap back into the guide tracks. Since the rearward face of each stop **39** forms a shoulder, the stops engage the guide tabs to impede re-extending the needle **62** after retraction.

The terms and expressions which have been employed are used as terms of description and not of limitation. There is no intention in the use of such terms and expressions of excluding any equivalents of the features shown and described or portions thereof. It will be recognized by those skilled in the art that changes or modifications may be made to the above-described embodiments without departing from the broad inventive concepts of the invention. For instance, as described above, the pocket **56** that protects the rear needle tip is formed from the lower slot walls **57** and the end wall **58**. However, the slot could be eliminated so that the pocket is formed simply by a lip projecting radially inwardly that prevents contact with the sharpened tip. It should therefore be understood that this invention is not limited to the particular embodiments shown and described herein, but is intended to include all changes and modifications that are within the scope and spirit of the invention as set forth in the claims.

What is claimed is:

1. A medical device operable in connection with a fluid container, comprising:

a housing having a rearward opening forming a socket configured to receive the fluid container;

a double-ended needle having a forward sharpened tip and a rearward sharpened tip operable between a projecting position in which the forward sharpened tip projects forwardly from the housing and a retracted position in which the forward sharpened tip is enclosed within the housing;

a biasing element biasing the needle rearwardly;

a guide for guiding the needle when the needle is displaced between the projecting position and the retracted position, comprising:

a track having an axial portion extending substantially parallel to the axis of the housing and a transverse portion extending transverse the axis of the housing; and

a guide tab connected with the needle and projecting into operative engagement with the track;

a needle retainer releasably retaining the needle against the bias of the spring wherein upon actuation of the needle retainer, the needle is released so that the biasing element displaces the needle rearwardly into the retracted position and the guide guides the needle during retraction so that the needle is tilted transverse the axis of the barrel in the retracted position;

a generally cylindrical insert lining the interior of the rearward portion of the housing, comprising:

a pocket formed in the wall of the insert for receiving and protecting the rearward needle tip when the needle is disposed in the retracted position;

a guide arm projecting forwardly and intersecting the track, the guide arm having a lower edge configured in the shape of the transverse portion of the track, wherein the lower edge of the guide arm forms a sidewall of the transverse portion of the track.

2. The device of claim **1** comprising a button having a manually actable surface for actuating the needle retainer.

3 The device of claim **1** wherein the spring circumscribes the needle while the needle is disposed parallel to the axis of the housing and also while the needle is disposed transverse the axis of the housing in the retracted position.

4. The device of claim **1** comprising a resiliently flexible pierceable cover covering and sealing the rearward needle tip so that upon inserting the fluid container into the housing, the rearward sharpened needle tip pierces the cover and the fluid container deforms the cover, wherein upon removing the fluid container, the cover resiliently extends to cover and

seal the rearward needle tip to prevent fluid from leaking out the rearward needle tip.

5. The device of claim 1 wherein the track comprises a groove formed in the interior wall of the housing.

6. The device of claim 1 wherein the housing comprises a locking aperture and the needle retainer comprises a radially deformable arm having a latch releasably engaging the locking aperture.

7. The device of claim 1 comprising a lock for locking the needle in the retracted position.

8. The device of claim 1 wherein the lock comprises a stop spaced from the rearward end of the track.

9. The device of claim 1 wherein the pocket is aligned with the transverse portion of the track.

10. The device of claim 1 comprising a second guide substantially similar to the first guide, spaced apart from and opposing the first guide.

11. A medical device operable in connection with a fluid container, comprising:

a housing having a rearward opening forming a socket configured to receive the fluid container;

a double-ended needle having a forward sharpened tip and a rearward sharpened tip operable between a projecting position in which the forward sharpened tip projects forwardly from the housing and a retracted position in which the forward sharpened tip is enclosed within the housing;

a biasing element biasing the needle rearwardly;

a guide for guiding the needle when the needle is displaced between the projecting position and the retracted position, comprising:

a track having an axial portion extending substantially parallel to the axis of the housing and a transverse portion extending transverse the axis of the housing; and

a guide tab connected with the needle and projecting into operative engagement with the track;

a needle retainer releasably retaining the needle against the bias of the biasing element wherein upon actuation of the needle retainer, the needle is released so that the biasing element displaces the needle rearwardly into the retracted position, and the guide guides the needle during retraction so that the needle is tilted transverse the axis of the barrel in the retracted position.

12. The device of claim 11 comprising a pocket adjacent the rearward end of the housing for receiving and shielding the rearward sharpened needle when the needle is disposed in the retracted position.

13. The device of claim 11 comprising a button having a manually actable surface for actuating the needle retainer

14. The device of claim 11 wherein the spring circumscribes the needle while the needle is disposed parallel to the axis of the housing and also while the needle is disposed transverse the axis of the housing in the retracted position.

15. The device of claim 11 comprising a resiliently flexible pierceable cover covering and sealing the rearward needle tip so that upon inserting the fluid container into the housing, the rearward sharpened needle tip pierces the cover and the fluid container to deform the cover, wherein upon removing the fluid container, the cover resiliently extends to cover and seal the rearward needle tip to prevent fluid from leaking out the rearward needle tip.

16. The device of claim 11 wherein the track comprises a groove formed in the interior wall of the housing.

17. The device of claim 11 wherein the housing comprises a locking aperture and the needle retainer comprises a radially deformable arm having a latch releasably engaging the locking aperture.

18. The device of claim 11 comprising a lock for locking the needle in the retracted position.

19. The device of claim 11 wherein the lock comprises a stop spaced from the rearward end of the track.

20. The device of claim 11 wherein the pocket is aligned with the transverse portion of the track.

21. The device of claim 11 comprising a second guide substantially similar to the first guide, spaced apart from and opposing the first guide.

22. A medical device operable in connection with a fluid container, comprising:

a housing having a rearward opening forming a socket configured to receive the fluid container,

a needle having a forward sharpened tip operable between a projecting position in which the forward sharpened tip projects forwardly from the housing and a retracted position in which the forward sharpened tip is enclosed within the housing;

a biasing element biasing the needle rearwardly;

a guide for guiding the needle when the needle is displaced between the projecting position and the retracted position wherein the guide comprises a track and a follower attached to the needle and in operative engagement with the track, and

a needle retainer releasably retaining the needle against the bias of the biasing element wherein upon actuation of the needle retainer, the needle is released so that the biasing element displaces the needle rearwardly into the retracted position, and the guide guides the needle during retraction, pivoting the needle so that the needle is tilted transverse the axis of the barrel in the retracted position.

23. The device of claim 22 wherein the needle comprises a rearward sharpened tip, and the device comprises a pocket disposed adjacent the rearward end of the housing for receiving and protecting the rearward needle tip to protect against inadvertent contact with the rearward needle tip.

24. The device of claim 23 wherein the pocket is aligned with the track.

25. The device of claim 22 comprising a button having a manually actable surface for actuating the needle retainer.

26. The device of claim 22 wherein the device comprises a needle hub attached to the needle, and the spring circumscribes substantially the length of the needle forward of the needle hub while the needle is disposed parallel to the axis of the housing and also while the needle is disposed transverse the axis of the housing in the retracted position.

27. The device of claim 22 wherein the needle comprises a rearward sharpened tip, and the device comprises a resiliently flexible pierceable cover covering and sealing the rearward needle tip so that upon inserting the fluid container into the housing, the rearward sharpened needle tip pierces the cover and the fluid container deforms the cover, wherein upon removing the fluid container, the cover resiliently extends to cover and seal the rearward needle tip to prevent fluid from leaking out the rearward needle tip.

28. The device of claim 22 wherein the track comprises a groove formed in the interior wall of the housing.

29. The device of claim 22 wherein the housing comprises a locking aperture and the needle retainer comprises a radially deformable arm having a latch releasably engaging the locking aperture.

30. The device of claim 22 comprising a lock for locking the needle in the retracted position.

31. The device of claim 22 wherein the lock comprises a stop spaced from the rearward end of the track.

32. The device of claim 22 comprising a second guide substantially similar to the first guide, spaced apart from and opposing the first guide.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 6,524,276 B1
DATED : February 28, 2003
INVENTOR(S) : Halseth et al.

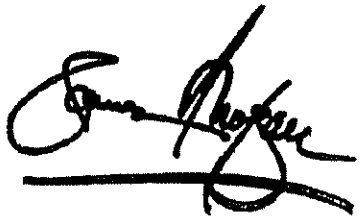
It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 4,
Line 34, "or" should read -- of --;

Column 10,
Line 66, insert Claim 33:
33. The device of claim 23 wherein the pocket is aligned with the track.

Signed and Sealed this

Seventeenth Day of June, 2003



JAMES E. ROGAN
Director of the United States Patent and Trademark Office

EXHIBIT B

US00D445183S

(12) **United States Design Patent** (10) **Patent No.: US D445,183 S**
McWethy et al. (45) **Date of Patent: ** Jul. 17, 2001**

(54) **NEEDLE-BEARING MEDICAL DEVICE**

(75) Inventors: **Robert T. McWethy**, Ventura; **Michael J. Botich**, Oxnard; **Thor R. Halseth**, Simi Valley, all of CA (US)

(73) Assignee: **MDC Investment Holdings, Inc.**, Wilmington, DE (US)

(**) Term: **14 Years**

(21) Appl. No.: **29/122,595**

(22) Filed: **Apr. 28, 2000**

(51) **LOC (7) Cl.** **24-02**
(52) **U.S. Cl.** **D24/130**; D24/147
(58) **Field of Search** D24/112, 130, D24/113, 146; 604/198, 192, 410, 195, 196, 110; 600/576, 578, 577, 583; 263/363, 365, 364

(56) **References Cited**

U.S. PATENT DOCUMENTS

D. 436,168	*	1/2001	Wilkinson et al.	D24/130
D. 436,169	*	1/2001	Wilkinson et al.	D24/130
4,813,426		3/1989	Haber .	
4,841,985	*	6/1989	Wanamaker	600/576
4,846,808		7/1989	Haber .	
4,850,374		7/1989	Diaz-Ramos .	
4,915,702		4/1990	Haber .	
4,947,863		8/1990	Haber .	
5,067,490		11/1991	Haber .	
5,086,780		2/1992	Schmitt	
5,219,333		6/1993	Sagstetter .	
5,353,806	*	10/1994	Heinzelman et al.	600/576
5,423,758		6/1995	Shaw .	
5,810,775		9/1998	Shaw .	
6,059,737	*	5/2000	Crawford	600/576

* cited by examiner

Primary Examiner—Ian Simmons
(74) *Attorney, Agent, or Firm*—Dann, Dorfman, Herrell and Skillman; Stephen H. Eland

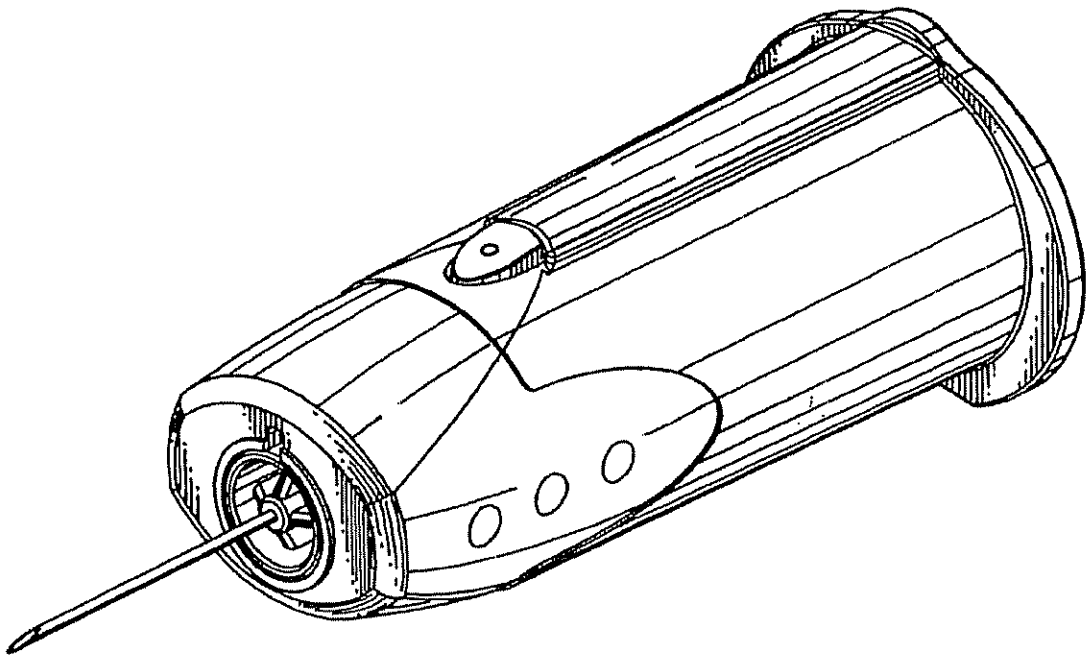
(57) **CLAIM**

The ornamental design for a needle-bearing medical device, as shown and described.

DESCRIPTION

FIG. **1** is a front perspective view of a needle-bearing medical device showing our new design;
FIG. **2** is a left-side view of the needle-bearing medical device shown in FIG. 1;
FIG. **3** is a right-side view of the needle-bearing medical device shown in FIG. 1;
FIG. **4** is a front elevational view of the needle-bearing medical device shown in FIG. **1**, with the back view being substantially a mirror of the front view;
FIG. **5** is a top plan view of the needle-bearing medical device shown in FIG. 1; and,
FIG. **6** is a bottom plan view of the needle-bearing medical device shown in FIG. **1**

1 Claim, 2 Drawing Sheets



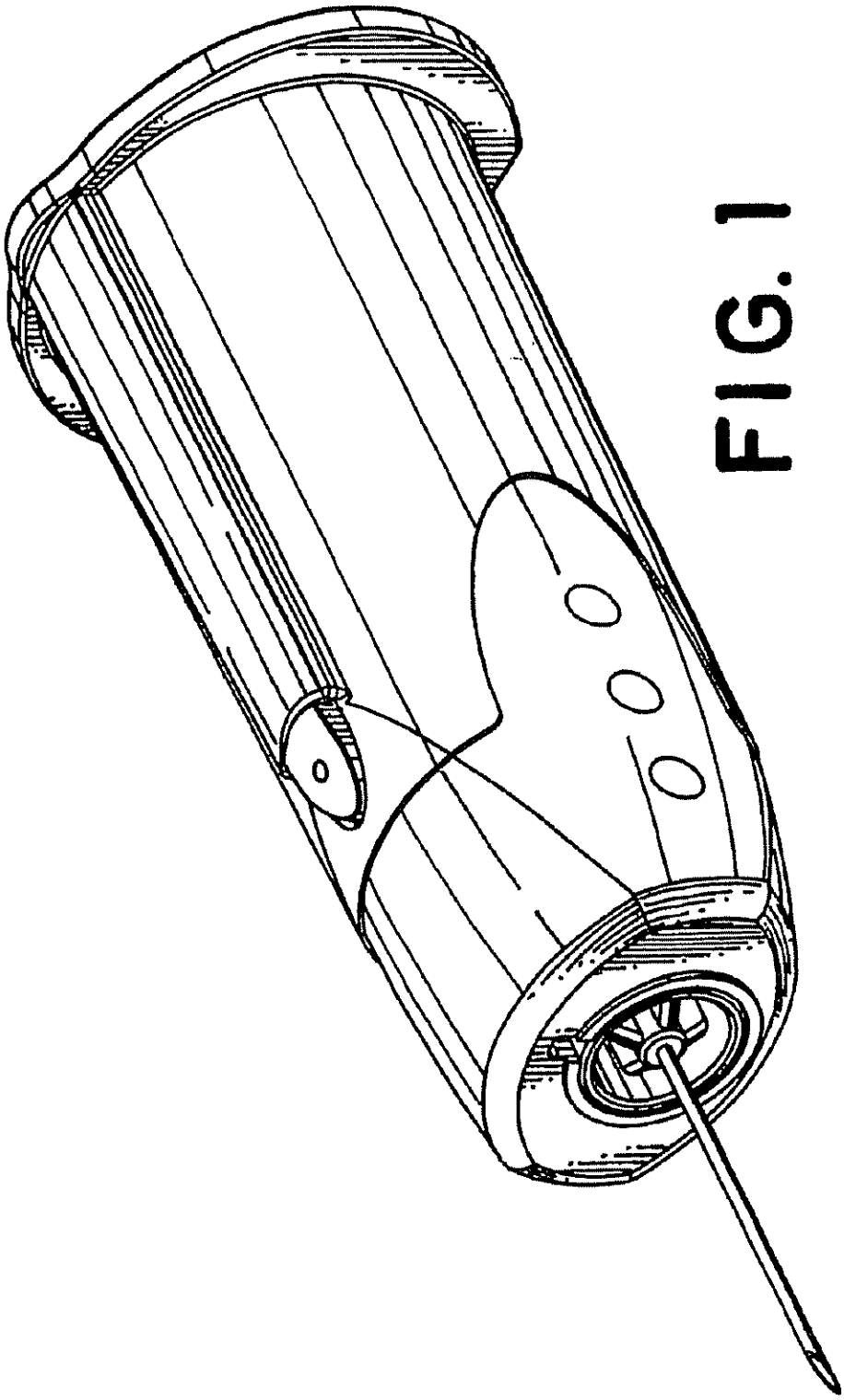


FIG. 1

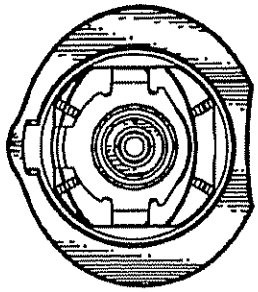


FIG. 3

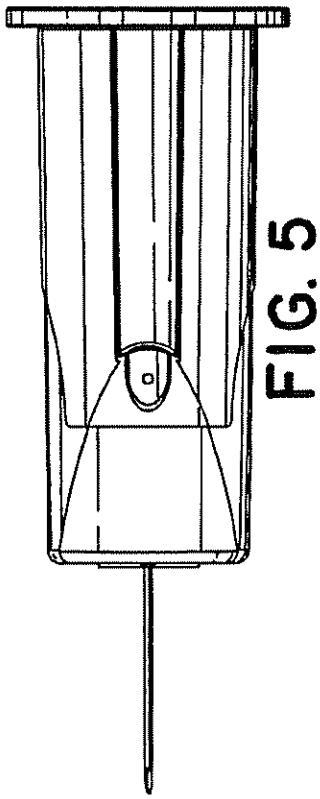


FIG. 5

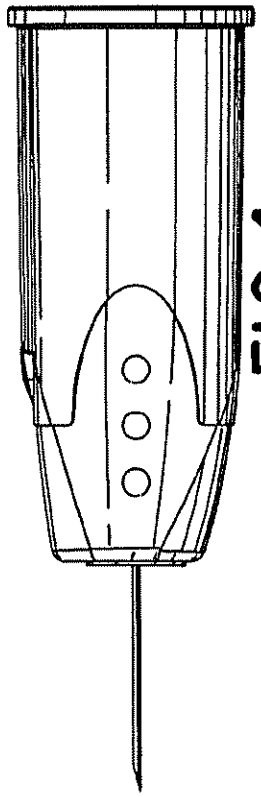


FIG. 4

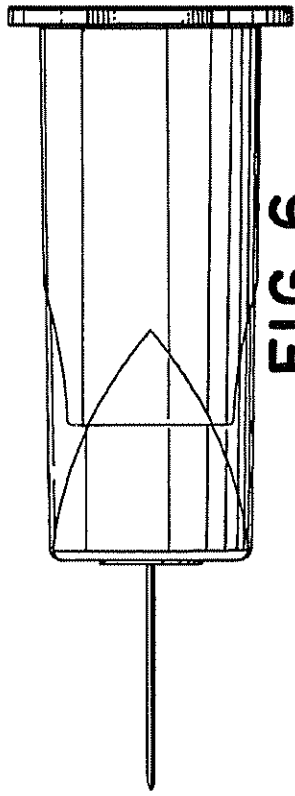


FIG. 6

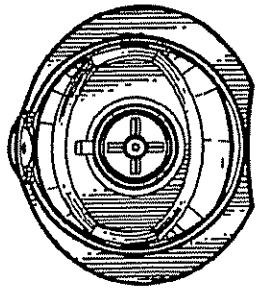


FIG. 2