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(54) Blood drawing device

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Description

FIELD OF THE INVENTION

[0001] The present invention relates to an apparatus for drawing bodily fluids, and particularly blood, from an animal.

BACKGROUND OF THE INVENTION

[0002] Intravenous blood collection assemblies have long been used to draw bodily fluids, such as blood, from patients. With respect to drawing blood in particular, the vessel or lumen from which the blood is drawn is often rather small and or not visible. If the needle tip is not in communication with the interior of the blood vessel during the procedure, the procedure is likely to be unsuccessful, causing error, undermining the integrity of the specimen, and the patient may be harmed additionally by the penetration of delicate underlying structures. Accordingly, confirmation of accurate placement of the needle tip into a blood vessel is desirable for blood drawing procedures.

[0003] Past intravenous blood collection assemblies have included mechanisms for indicating when a needle tip is in communication with the interior of a blood vessel. These needle kits have included a transparent portion in the needle body from which the presence of blood can be observed. The observation of blood in the needle body is known as "flash," Flash detection has been less than satisfactory for many such collection assemblies. In some instances, the flow of blood into the transparent portion of the needle body is impeded by air backpressure in the needle, and thus flash confirmation is not visible or delayed. This delay can impede the determination of the precise moment at which the needle tip enters the blood vessel, which may cause the healthcare worker inserting the needle to miss or perforate the vessel and penetrate into delicate surrounding structures. In other instances, while flash occurs, the visual indication of flash is not easily detected because the amount of flash is small or obscured due to the positioning of the collection assembly. Accordingly, there is a need for a blood-drawing device that provides flash relatively rapidly and to an extent that a user may readily detect it.

SUMMARY OF THE INVENTION

[0004] Responsive to the foregoing challenges, Applicant has developed a flexible sleeve for connection to a blood drawing device, adapted to receive a cannula of said blood drawing device said sleeve comprising: an open end, a closed end, and an air-permeable and at least partially blood impermeable wall.

[0005] Applicant has still further developed an innovative method of making an air permeable at least partially blood impermeable flexible sleeve for connection to a blood drawing device comprising the steps of: providing a hydrophobic matrix material; mixing the hydrophobic matrix material with hydrophilic porous agent; forming a flexible sleeve for connection to a blood drawing device from the mixture of hydrophobic matrix material and hydrophilic porous agent; and drying the mixture of hydrophilic porous agent sufficiently to render the flexible sleeve air-permeable, wherein the hydrophilic porous agent swells upon contact with aqueous liquid.

[0006] It is to be understood that both the foregoing general description and the following detailed description are exemplary and explanatory only, and are not restrictive of the invention as claimed.

BRIEF DESCRIPTION OF THE DRAWINGS

[0007] In order to assist the understanding of this invention, reference will now be made to the appended drawings, in which like reference characters refer to like elements.

[0008] Figure 1 is an exploded pictorial side view of a first arrangement of a blood drawing device.

[0009] Figure 2 is a side view in cross-section of a first arrangement of a blood drawing device prior to the insertion of a sample collection tube.

[0010] Figure 3 is a side view in cross-section of the rear cannula portion of a first arrangement of a blood drawing device.

[0011] Figure 4 is a side view in cross-section of a first arrangement of a blood drawing device after the insertion of a sample collection tube.

[0012] Figure 5A is a side view in cross-section of a second arrangement of a blood drawing device incorporated into a Luer-type blood drawing device in combination with a standard hypodermic needle or I.V. infusion set ("butterfly needle").

[0013] Figure 5B is a side view in cross-section of an alternative Luer-type hub for use with the Luer-type blood drawing device shown in Fig. 5A.

[0014] Figure 6 is a side view in cross-section of a third arrangement of a blood drawing device.

[0015] Figure 7 is a side view in cross-section of the rear cannula portion of a fourth arrangement of a blood drawing device.

[0016] Figure 8 is a side view in cross-section of the rear cannula portion of a fifth arrangement of a blood drawing device.

[0017] Figure 9 is a side view of a flexible sleeve constructed in accordance with a first embodiment of the present invention.

[0018] Figure 10 is a pictorial view of the venting member and porous spacer shown in Figure 8.

[0019] Figure 11 is a pictorial view of a second embodiment of the present invention.

[0020] Figure 12 is a pictorial view of the porous collar shown in Figure 11.

[0021] Figure 13 is a side view in cross-section of a blood flow control mechanism that may be used with various embodiments of the present invention and/or independently in accordance with an eighth embodiment of

the invention.

[0022] Figure 14 is a side view in cross-section of a rear cannula portion of a third embodiment of the present invention.

DETAILED DESCRIPTION OF EMBODIMENTS OF THE INVENTION

[0023] Reference will now be made in detail to a first arrangement of a blood drawing device which is illustrated in the accompanying drawings. With reference to Fig. 1, an exploded pictorial view of a blood-drawing device **10** is shown. The blood-drawing device **10** includes a front cannula **130,** a central body **100,** a venting member **160,** a rear cannula **140,** and a flexible sleeve **150.** A guide tube **116** may be connected to the central body **100.** The front cannula **130** and the rear cannula **140** may each have a generally elongated cylindrical body defining an elongated fluid passage extending from one end of the cannula to the other end. The front cannula **130** may extend from the front end of the central body **100** and terminate at a tapered or pointed end **132,** which is adapted to be inserted into a lumen. The rear cannula **140** may extend from the rear of the central body **100** and terminate at a tapered or pointed end **142.** The sleeve **150** may isolate the rear cannula **140** from the ambient, wherein the ambient includes any space outside of the sleeve **150,** irrespective of whether or not the space is contained within the guide tube **116** or any other structure.

[0024] With reference to Figs. 1 and 2, the central body **100** may include one or more constituent elements, such as a threaded connector **112,** which may be integrally formed with, or connected to the central body using adhesive, male-female interfaces, threaded interfaces, or any other connection means. The central body **100** may include an annular ring **104,** radiating fins **105,** or like features, extending from the central body and which may be adapted to aid a user in handling the device **10.** A fluid passage **110** within the central body **100** may communicate with, and in the arrangement shown, be connected to, the inner portion **134** of the front cannula **130** and the inner portion **144** of the rear cannula **140,** respectively, using adhesive, threaded interfaces, pressure fit, or other connection means. Alternatively, the central body **100** may be integrally formed with the front and/or rear cannulae **130** and **140.** It is also appreciated that the front and/or rear cannulae may be transparent or translucent, in whole or part, to provide flash detection

The fluid passage **110** may be defined by the opening within the central body between the front and rear cannulae when the cannulae are directly connected to the central body. The fluid passage **110** may be adapted to receive a sufficient amount of fluid to allow observation of the fluid (*i.e.*, "flash") from outside the blood-drawing device **10.** At the same time, the fluid passage **110** may have a sufficiently small volume so as to rapidly fill with fluid during the use of the blood-drawing device.

[0025] The central body **100** may be constructed of plastic material suitable for medical use. Further, all, or portions, of the central body 100 may be transparent, translucent, connected to transparent or translucent I.V. tubing, or otherwise adapted to permit detection of fluids passing through the central body and/or I.V. tubing from a vantage point outside of the blood-drawing device 10. For example, with particular reference to Fig. 1, the central body **100** may include a transparent wall that is adapted to permit the observation of "flash" when it occurs. In an alternate arrangement the side wall of the central body **100** also may be adapted to magnify or otherwise enhance the detection of fluid passing through the central body, although it is appreciated that a magnifying or enhancement feature is not necessarily required.

[0026] With particular reference to Fig. 2, the venting member **160** (*i.e.*, a means for venting air) may be inserted over the rear cannula **140** and pressed against or near to the rear portion of the central body **100** (*i.e.,* the portion proximate to the rear cannula **140**). The venting member **160** may form a seal against the rear cannula that is sufficient to prevent blood from escaping past the venting member.

The venting member **160** may be gas, and particularly air, permeable, but at least partially impermeable to a liquid, such as blood. The venting member **160** may be substantially porous for gas constituents less than about 5 microns in size, and substantially non-porous for liquid constituents about 5 microns or greater in size.

The venting member 160 may be constructed of any of a number of materials that provide the desired level of porosity, which may include, but are not limited to sintered, layered, rolled, foamed, perforated, or impregnated, hydrophyllic/hydrophobic compositions, porous polyethylene, porous polypropylene, porous polyfluorocarbon, absorbent paper, materials impregnated with dilute Russell Viper venom molded fiber, fiberglass, felt, granular starch, cellulose, polyacrylamide gel, hydrogel, a molded admixture of porous hydrophobic/hydrophyllic granules and sufficiently low density silicone, molded open cell polyurethane, and like polymeric materials. Examples of materials that may be used to construct the venting (i.e., porous) member **160** are discussed in U.S. Patent No. 4,207,870 to Eldridge, and U.S. Patent No. 4,340,068 to Kaufman. The venting member **160** shown in Fig. 2 includes a base portion nearest the central body **100,** a tapered portion furthest from the central body, and an annular recess in between the tapered portion and the central body. The tapered portion may facilitate the insertion of the flexible sleeve **150** over the venting member **160** and the annular recess may facilitate retention of the flexible sleeve after it is so inserted. It is also appreciated that the venting member **160** may have any shape be it cylindrical, spherical, tapered, irregular, or other.

[0027] The rear cannula **140** may communicate with, and in the arrangement shown, extend out of, the central body **100,** and through the venting member **160.** The rear

cannula **140** may terminate at a tapered or pointed end **142,** which is adapted to be inserted into a fluid sample tube (shown in Fig. 4), or connected to a fluid collection reservoir. A flexible sleeve **150** may be disposed over and around the rear cannula **140.** The flexible sleeve **150** may be stretched over the tapered portion on the end of the venting member **160,** or otherwise contact the venting member **160.** The flexible sleeve **150** may be made of a shape memory material, such as elastic rubber or elastomeric silicone or latex, or the like, which will return to the shape shown in Fig. 2 as long as no other structure obstructs it. Examples of materials that may be used to construct the flexible sleeve 150 are discussed in U.S. Patent No. 3,877,465 to Miyake, U.S. Patent No. 5,086,780 to Schmitt, U.S. Patent No. 6,110,160 to Farber, U.S. Patent No. 6,533,760 to Leong, U.S. Patent Pub. No. US 2002/0004647 A1 to Leong, and U.S. Patent Pub. No. US 2003/0078544 A1 to Chen.

It is appreciated that any suitable material may be used for the flexible sleeve.

[0028] A generally cylindrical guide tube **116** may be connected to the threaded connector **112** by interlocking threads **114** and **120,** respectively. When connected to the central body **100,** the guide tube **116** may have an open end **118** adapted to receive a fluid sample container (shown in Fig. 4). The guide tube **116** may extend coaxially with the rear cannula **140** sufficiently beyond the tapered end **142** of the rear cannula to provide some degree of protection against inadvertent "needle sticks" by a user of the blood-drawing device **10** as well as to guide the reception of a fluid sample container.

[0029] The function of the first arrangement of the blood-drawing device 10 discussed above will now be described with reference to Figs. 2-4. With reference to Fig. 2, the tapered end **132** of the front cannula **130** (or some extension thereof) may be inserted into a fluid containing body lumen prior to the insertion of a fluid sample container into the guide tube **116.** The front cannula 130 many be inserted into a lumen containing a visually detectable fluid, such as blood. At the time that the front cannula **130** is inserted into the body lumen, it is assumed that the internal passages within the blood-drawing device (*i.e.*, the passage through the front cannula **130,** the fluid passage **110,** the passage through the rear cannula **140,** and the space inside the flexible sleeve **150**) may be filled with atmospheric air or some other gas. When the front cannula **130** establishes communication with the fluid in the body lumen, fluid pressure in the lumen may force the fluid through the front cannula **130** towards the fluid passage **110.**

[0030] With reference to Fig. 3, the flow of fluid **200** through the front cannula may begin to compress the air in the fluid passage **110,** the rear cannula **140,** and the space between the rear cannula and the flexible sleeve **150,** driving the air towards the venting member **960.** As blood flows into the device, all or a portion of the air in the device may flow through venting member **160** (*i.e.*, be vented) because the venting member is gas permeable. As a result, there may be insufficient air pressure within the fluid passage **110** to resist the flow of the fluid **200** into the fluid passage **110,** where it may be detected or observed as "flash" by a user. It is appreciated that "flash" may be detected at any point along the device that includes a transparent or translucent member, which may include, but not be limited to, a transparent or translucent cannula, central body, I.V. tubing, flexible sleeve, or other constituent member. After fluid fills the blood drawing device **10** and reaches the venting member **160,** fluid leakage past the venting member may be prevented or reduced because the venting member may be at least partially impermeable to liquids, such as blood. As a result, the blood drawing device **10** may provide for detection of "flash" when the front cannula **130** is inserted into a body lumen (such as a vein) containing fluid (such as blood) to be withdrawn prior to the insertion of a fluid sample container into the guide tube **116** and the penetration of the rear cannula into the fluid sample container.

[0031] With reference to Fig. 4, after the detection of "flash" within the fluid passage **110,** a fluid sample container **170** may be used to collect a sample of the fluid flowing from the body lumen. The fluid sample container **170** may have a generally cylindrical outer wall, which is preferably, but not necessarily, transparent. The outer wall may define a collection chamber **174,** which is preferably maintained in a vacuum condition prior to use of the container **170.** A stopper **172** may be used to seal the open end of the container **170** so as to prevent air leakage into the collection chamber **174** prior to use of the container. One example of a commercially available vacuum container that may be used with various embodiments of the invention is a Vacutainer sold by Becton Dickinson & Co. of Franklin Lakes, N.J.. Construction of vacuum containers, such as the one noted above, and the selection of materials therefore, are well known in the art.

[0032] In order to collect a fluid sample, the container **170** may be slid into the guide tube **116** through the opening **118** until it contacts the flexible sleeve **150.** As the container **170** is pushed further into the guide tube **116,** the tapered end **142** of the rear cannula presses into and pierces both the flexible sleeve **150** and the stopper **172.** The flexible sleeve is pushed down towards, and may gather around, the venting member **160,** as shown in Fig. 4. When the tapered end **142** of the rear cannula **140** is past the stopper **172,** the pressurized fluid in the body lumen may readily flow through the blood-drawing device **10** to the vacuum space in the collection chamber **174.**

[0033] After a first container **170** is full of fluid, it may be removed from the blood drawing device **10** for replacement by a second container. As the first container **170** is withdrawn from the guide tube **116,** the flexible sleeve **150** may follow until it regains its original shape because it is constructed of shape memory material. The openings in the stopper **172** and the flexible sleeve **150,** which were created by the rear cannula **140,** may collapse or "heal" when the rear cannula is removed due to the nature

of the material used to construct the stopper and the flexible sleeve. As a result, the fluid sample in the first container **170** may be sealed within it, and the fluid within the flexible sleeve **150** may be prevented from substantially leaking out of it. Thereafter, a second container **170** may be inserted into the guide tube **116** for collection of a fluid sample in the manner described above.

[0034] A second arrangement of blood drawing device is shown in an exploded side view in Fig. 5A. With reference to Fig. 5A, a Luer-type blood-drawing device is provided with a venting member **160.** The central body **100** may be provided with an enlarged fluid passage **110** which may improve flash visibility. It is appreciated that the enlarged fluid passage could have any of a number of different shapes and sizes, which may be uniform or non-uniform over the length of the passage. It is further appreciated that the fluid passage **110** could have any of a variety of shapes and sizes without departing from the intended scope of the invention.

[0035] The butterfly needle **180** may be connected to the Luer-type hub **102** via a butterfly connection tube **182.** The butterfly needle **180** may include a butterfly (*i.e.*, front) cannula **184** and one or more wings **186.** The butterfly cannula **184** may be inserted directly into the body lumen for blood collection. Flash may be observed in the transparent or translucent butterfly connection tube **182,** in which case the central body **100** need not be transparent or translucent (although it could be).

[0036] With continued reference to Fig. 5A, known butterfly needles may use a butterfly connection tube **182** approximately 12 or more inches in length. This length of tubing is used so as to provide a sufficiently long column of air to permit flash observation when the blood-drawing device **10** is not provided with an air vent. Specifically, when a butterfly connection tube is used without an air vent, the flow of fluid through the butterfly needle may compress the volume of air in the butterfly connection tube **182,** the fluid passage **110,** the rear cannula **140,** and the space between the rear cannula and the flexible sleeve **150**. Because there is no vent provided, as blood flows into the device, the air in the device exerts an increasing level of backpressure on the blood, which may prevent blood flow and flash detection. The inclusion of a butterfly connection tube approximately 12 inches in length or greater increases the relative volume of air in the blood collection device. The increased volume of air in the device may permit flash detection before the air backpressure in the device rises to a level that prevents further blood flow into the device and could frustrate flash detection. Butterfly connection tubes of this length may be coiled in packaging, and retain some coil memory after they are removed from their packaging. Previously coiled butterfly connection tubes may resist being straightened for use and have an inherent bias towards returning to their coiled shape. Accordingly, manipulation of a butterfly needle attached to a previously coiled butterfly connection tube may be difficult due to the connection tube's tendency to recoil. This action can be the cause of accidental needle sticks for the healthcare worker and the patient. Furthermore, the coil memory of the tubing may make handling generally difficult for lumen insertion, and/or maintenance of the needle in the lumen.

[0037] The butterfly connection tube **182** used in the device shown in Fig. 5A may be less than approximately 12 inches in length, and more preferably, may be only a few inches in length as a result of the inclusion of a venting member **160** in the blood-drawing device **10.** The inclusion of the venting member **160** may obviate the need for a relatively long column of air in the butterfly connection tube that otherwise may be needed to indicate flash. The use of a shortened butterfly connection tube **182** may also obviate the need to coil the tube prior to use, thereby eliminating the issues associated with coil memory in the tube, as well as make it possible to use rigid or semi-rigid connection tubes that may better enable placement of the front cannula into the body lumen.

[0038] With reference to Fig. 13, a butterfly needle **180,** such as shown in Fig. 5A, may optionally be provided with a blood flow control member **190.** The blood flow control member **190** may include a slideable control valve **188** surrounding the distal end of the butterfly connection tube **182** and the butterfly cannula **184.** The slideable control valve **188** may include an inner convex boss **189** adapted to restrict flow through the butterfly cannula **184** when positioned near the inner butterfly cannula end **185.** Flow through the butterfly cannula **184** may be controlled by manually sliding the control valve **188** so that the inner convex boss **189** is nearer to or more removed from the inner butterfly cannula end **185.** The slideable control valve **188** may completely or partially shield the distal end of the butterfly cannula **184** when it is positioned to block or restrict flow through the butterfly cannula. Control over blood flow through the butterfly cannula **184** may be used to avoid collapsing small or low pressure lumens (typical of children and the elderly) during negative pressure conditions experience during blood drawing procedures. It is appreciated that the blood flow control member **190** could optionally be used with other arrangements that do not incorporate a butterfly needle. It is also appreciated that the flow control member **190** may be used with any conventional I.V. infusion or fluid drawing device. It is further appreciated that alternative control valve **188** designs are known in the art and may be substituted for the afore-described design.

[0039] It is further appreciated that in an alternative arrangement of the blood drawing device shown in Fig. 5A, the butterfly needle **180** may be modified to eliminate the butterfly wings **186.** More specifically, the embodiment shown in Fig. 5A could be modified so that the butterfly cannula **184** is replaced by a conventional front cannula, which may be connected to the central body **100** by any elements, including but not limited to a flexible tube, rigid tube, or semi-rigid tube, any one of which may be constructed of transparent or translucent material to indicate flash.

[0040] A variation of the arrangement of the blood

drawing device shown in Fig. 5A is shown in Fig. 5B, in which the butterfly needle **180** is replaced by a front cannula **130** connected directly to the Luer-type hub **102.** The Luer-type hub **102** is adapted to connect to the Luer-type central body **100** in accordance with known methods.

[0041] A third arrangement of a blood drawing device is shown in Fig. 6. With reference to Fig. 6, a porous member **160** may be inserted over the rear cannula **140** and slightly separated from the rear portion of the central body **100** (*i.e.*, the portion proximate to the rear cannula **140**), leaving a small space **161** between the central body and the porous member. The porous member **160,** itself, and/or the seal it forms against the rear cannula, may not completely prevent blood from escaping past the porous member. In such instances, the porous member **160** may be constructed of material that is porous to gas (air) and somewhat, but not perfectly, non-porous to blood. The porous member **160** may preferably include a tapered portion, however, it is appreciated that the porous member may have any alternative shape, such as cylindrical, spherical, irregular, or the like, without departing from the intended scope of the invention.

[0042] In arrangements in which the porous member **160** is not completely non-porous to blood, a gas or air porous and/or liquid absorbent spacer **168** may be inserted behind the porous member **160** in the space **161.** The porous spacer **168** may be constructed of any of a number of materials that are porous to gas (air), and partially, substantially, or completely non-porous to liquids such as blood, and/or partially or completely absorbent of such liquids. For example, the porous spacer **168** may be constructed of sintered, layered, rolled, foamed, perforated, or impregnated hydrophyllic/hydrophobic compositions, porous polyethylene, porous polypropylene, absorbent paper, molded fiber fiberglass, felt, granular starch, cellulose, polyacrylamide gel, hydrogel, or the like. It is appreciated that in some embodiments the porous spacer **168** may permit some blood seepage past it, however, it is expected that the porous spacer may reduce or slow such seepage. After the porous spacer **168** is positioned in the air space **161,** the flexible sleeve **150** may be stretched over the porous member **160** and a portion, or none, of the porous spacer **168,** so long as at least of portion of the porous spacer remains in communication with the ambient.

[0043] A fourth arrangement of a blood drawing device is shown in Fig. 7. With reference to Fig. 7, a rear cannula **140,** non-porous member **162,** and air space 161 arrangement, similar to that shown in Fig. 6, are used. The flexible sleeve **150** is modified from that shown in earlier embodiments to include a side tubulation **154** and a porous insert **152.** The porous insert **152** may be any size and may be constructed of sintered polyethylene, perforated plastic, porous fiber, rolled fiber, or the like. It is appreciated that in some embodiments the porous insert **152** may permit some blood seepage past it, however, it is expected that the porous insert may reduce or slow such seepage. As a result of the inclusion of the porous insert **152** between the interior of the sleeve **150** and the ambient, air in the blood-drawing device 10 may vent from the interior of the sleeve through the porous insert **152** when the device is used to draw blood. Blood within the sleeve **150** may be prevented however, at least initially, from passing the porous insert **152.**

[0044] A fifth arrangement of a blood drawing device is shown in Figs. 8 and 10. With reference to Figs. 8 and 10, a non-porous venting member **166** may be inserted over the rear cannula **140** and slightly separated from the rear portion of the central body **100** (*i.e.*, the portion proximate to the rear cannula **140**), by a porous spacer **168** between the central body and the non-porous venting member. The non-porous venting member **166** may form a seal against the rear cannula that is sufficient to prevent blood from escaping past the non-porous venting member along its surface in contact with the rear cannula. The non-porous venting member **166** may be constructed of material, such as plastic suitable for medical use, which is non-porous to both gas (air) and blood. The outer surface of the non-porous venting member **166** may include one or more grooves, channels, bumps, or like features **167** (collectively "venting features **167**") that permit the passage of air. It is appreciated that the venting features **167** may be very small (of a size capable of permitting the passage of air molecules). Such small venting features may inherently restrict the passage of blood molecules, which typically may be larger that air molecules. The non-porous venting member **166** may preferably have a tapered tip and adapted to receive a flexible sleeve **150** stretched over it.

[0045] A porous spacer **168** may be inserted between the non-porous venting member **166** and the central body **100.** The porous spacer may be constructed of any of a number of materials that are porous to gas (air), and partially, substantially, or completely non-porous to liquids such as blood. For example, the porous spacer **168** may be constructed of sintered polyethylene, perforated plastic, porous fiber, rolled fiber, or the like. It is appreciated that in some embodiments the porous spacer **168** may permit some blood seepage past it, however, it is expected that the porous spacer may reduce or slow such seepage.

[0046] With continued reference to Figs. 8 and 10, the flexible sleeve **150** may be stretched over the non-porous venting collar **166** and at least a portion of the porous spacer **168** such that at least of portion of the porous spacer remains in direct communication with the ambient. Air in the blood drawing device may vent from the interior of the sleeve **150** past the venting features **167** on the non-porous venting member **166** and through the porous spacer **168** to the ambient when the device is used to draw blood. Blood within the sleeve **150** may be prevented however, at least initially, from passing the porous spacer **168** as a result of the nature of the material in the porous spacer and the relatively small passageways provided by the venting features **167.**

[0047] A first embodiment of the present invention is shown in Fig. 9. With reference to Fig. 9, an air-permeable, completely or partially blood-impermeable flexible sleeve **151** is provided. The air-permeable sleeve **151** may be used in conjunction with or independently of the above-referenced embodiments of the present invention. A known flexible sleeve is described in U.S. Patent No. 3,877,465 to Miyake. In the present embodiment of the invention, the elastic sheath material making up the wall of the sleeve **151** may be constructed of a material that is largely air-permeable, but partially, largely or entirely impermeable to blood. The air-permeable sleeve **151** may be used to isolate the rear cannula **140** of a blood drawing device from the ambient in the same manner as conventional sleeve may isolate rear cannulae. During a blood drawing procedure using a device not equipped with a means for venting air from the sleeve , blood from a lumen may be slowed or prevented from entering the device due to air back pressure in the device. In these devices the air in the device may be trapped because there is no vent provided. In the present embodiment, an air-permeable sleeve 151 replaces a conventional sleeve on the blood drawing device. The air-permeable sleeve **151** may provide a pathway to vent air from the device interior, through the sleeve wall, to the ambient. As the air is vented, the blood filling the device may contact the air-permeable sleeve **151.** However, the air-permeable sleeve **151** may prevent or retard the flow of blood through its wall because the pore size of the air-permeable sleeve may be large enough to allow the passage of air, but too small to allow much or any blood to pass. This air passage-blood blockage may permit blood to fill the needle and/or the sleeve **151** more readily because there is reduced or no air back pressure inhibiting the flow of blood into the blood drawing device. As a result, a blood drawing device equipped with the air-permeable sleeve **151** may indicate flash (the visual indication of blood flow into the needle) more readily. The air-permeable sleeve **151** may be used with conventional needle drawing or infusion sets (such as butterfly needles), hypodermic needles, or the like, to enhance flash indication.

[0048] The air-permeable sleeve **151** may be made of any suitable material that is completely or at least partially air-permeable and substantially blood impermeable, such as for example, low density polyethylene or low density rubber. One example of a method of making such material is described in U.S. Patent No. 5,649,442. A second example may be made of crumbed material of sufficiently low density/high flexibility to allow the required flexibility in spite of the use of thermal binders like polyethylene. Low density material such as low density silicone may be sifted using a #80 mesh and mixed with #100 mesh low density polyethylene. This mixture may be heated at approximately 280° F and injected into a cavity mold to form the selectively porous sleeve **151.**

[0049] An air-permeable sleeve may be constructed of porous material formed from the combination of a hydrophobic porous material with a hydrophilic porous agent. The hydrophobic porous material, for example, may be a polymeric matrix of either thermoplastic resins such as polyvinyl chloride or copolymers thereof, or synthetic or natural thermosetting rubber-like polymers. In a second example, the polymeric matrix may be rubber-like polymers combined with additives such as antidegradants, cross-linking agents, cure inhibitors, platinum and other type catalysts, inert fillers, or like materials used to compound thermosetting compounds, and intimately mixed with a hydrophilic porous agent such as silica hydrogel, precipitated hydrated silica, for example such as that sold under the trademark Hi-Sil from PPG Industries, or polyacrylamide gel, cross-linked homopolymer of acrylamide, for example such as that sold under the trademark Agrosoake from Agrosoake International, inert fillers and/or water or solvent soluble porosics. In a third example, the polymeric matrix may be made of a synthetic or natural thermosetting polymer or copolymer, such as those that may be made in accordance with the methods disclosed in U.S. Patent No. 4,548,835 to Takahashi, et al. and U.S. Patent No. 4,153,760 to Sundberg et al, for example.

[0050] The porous agent may be prepared by polymerizing acrylamide in the presence of an aqueous sodium carbonate to produce a partially hydrolyzed, lightly cross-linked, polyacrylamide gel in accordance with the method disclosed in U.S. Patent No. 3,022,279 to Proffitt, for example.

The polyacrylamide gel may be produced in bead or granular form using an inverse suspension polymerization method for water-soluble monomer, which is disclosed in U.S. Patent No. 2,982,749 to Friedrich et al., for example,

[0051] In one embodiment, for example, the hydrophilic granules may be added to the hydrophobic material in sufficient quantities to create a hydrophilic/hydrophobic porous material. The porosity of the hydrophobic material may be manifested by a network of voids/pores extending throughout the matrix or binder, between neighboring particles of the dispersed filler and portions of the polymeric matrix, which may be achieved by the shrinking of the swollen hydrophilic granules during the dehydration/curing phase. The resultant degree of porosity may be controlled by the amount of water or water substitute added to the polymeric matrix binder material during the mixing phase, the vulcanization of the polymeric matrix (such as for example, under hydrostatic conditions in a steam autoclave to a state of cure using the pressurized steam as a source of heat), the proportion and size of the hydrophilic granules added, the duration of the mixing phase, and the wall thickness of the elastomeric sleeve. The hydrophilic granules may be mixed with a normally hydrophobic binder (and water or a water substitute may be added to control porosity) in a mixing type extruder.

[0052] When this material is formed into an air-permeable flexible sleeve **151,** water-based liquids such as blood may rapidly soak into the pores/voids containing

the granular material, causing the granules to swell and seal the pores/voids contained within the polymeric matrix. Thus, the air-permeable flexible sleeve, which is initially permeable to air, may become relatively impermeable to liquids, such as blood, due to the swelling of the moisture reactive granules entrapped within the pores/voids within the polymeric matrix.

[0053] A second embodiment of the present invention is shown in Figs. 11 and 12. With reference to Figs. 11 and 12, a flexible sleeve **150** may be provided with one or more openings or perforations **156** extending through the wall of the sleeve. The openings **156** may be relatively small, only needing to be capable of permitting the passage of air molecules. A porous collar **157** constructed of sintered polyethylene, perforated plastic, porous fiber, rolled fiber, or the like, may be provided over the openings **156.** The flexible sleeve **150** may be stretched over the non-porous member inserted over the rear cannula, (such as non-porous member **162** shown in Fig. 7). Air in the blood drawing device may vent from the interior of the sleeve **150** past the openings **156** in the flexible sleeve wall and through the porous collar **157** to the ambient when the device is used to draw blood. Blood within the sleeve **150** is prevented however, at least initially, from passing the porous collar **157** as a result of the nature of the material making up the porous collar and potentially by the relatively small passageways provided by the openings **156.**

[0054] An alternative embodiment of the present invention is shown in Fig. 14, in which the venting member **160** is spaced from the central body **100** and the flexible sleeve **150** envelopes the entire side wall of the venting member. A portion of the base end wall of the venting member **160** is exposed to the ambient to permit air to vent. In a further alternative, a porous spacer **168** may be disposed in the air space **161** to block or absorb any blood seepage past the venting member.

[0055] Each of the embodiments of the present invention shown in all of the afore-noted figures may also utilize a transparent or translucent flexible sleeve **150** to provide flash detection. An example of a transparent sleeve is disclosed in U.S. Patent No. 3,886,930 to Ryan. Use of a transparent or translucent sleeve **150** may make it unnecessary for the central body **100** or other elements of the device to be constructed of transparent or translucent material because the flash may be detected through the wall of the sleeve itself and thereby allow for the retrofitting of known blood-drawing devices to provide air venting and flash detection without other modification of the device. Use of a transparent or translucent sleeve **150** may also obviate the need to have discreet front and rear cannulae **130** and **140.** The front and rear cannulae may be constructed from a single integral piece of material because in this embodiment of the invention there may be no need to view flash in the central body **100.**

[0056] Each of the arrangements and embodiments described above may also be modified such that the porous member **160** (Figs. 1-6), the porous collar **157** (Figs. 11-12), the porous insert **152** (Fig. 7), or the porous spacer **168** (Figs. 6, 8 and 10) includes or is constructed of any one or more of a number of substances that may permit air venting, and limit and reduce blood seepage, but not completely prevent blood seepage through the particular porous structure. Such materials include absorbent pleated or rolled paper, molded fiber or fiberglass, felt, sintered compositions of hydrophilic/hydrophobic materials such as polyethylene and polyacrylamide gel, and/or any other material capable of venting air but impeding the passage of liquids.

[0057] For example, hydrophilic and/or hydrophobic substances such as polyethylene and granular starch, cellulose, polyacrylamide gel, or the like may be used. Such substances are known in the art, and may be used to permit gas (*e.g.*, air) to flow through them, but absorb or block liquid substances. Accordingly, a porous member, collar, insert, or spacer, comprised of these materials may be used to permit the air in a blood drawing device to vent past it until it is contacted by a liquid, such as blood, at which time the blood may be absorbed.

[0058] Similarly, glass powder or fiber may be used to simulate clotting, or a clotting agent, such as dilute Russell Viper Venom, may be used to permit air venting with little or reduced blood seepage. Russell Viper Venom is known in the art as a clotting agent. A porous member, collar, insert, or spacer impregnated with a clotting agent or simulating clotting agent may be used to permit the air in a blood drawing device to vent until it is contacted by blood, at which time the blood may clot or act as clotted and reduce further blood seepage through the porous member, collar, insert or spacer. As a result, use of hydrophilic and/or clotting agents in the previously described porous member, collar, insert, or spacer may permit improved blood flow into a blood drawing device and flash detection.

[0059] A multitude of different means for venting air are described above. It is appreciated that various embodiments of the invention may include any type of means for venting air disposed between a flexible sleeve covering the rear cannula of a blood drawing device and an ambient, including, but not limited to one or more air porous materials provided individually or in combination, and/or combinations of air porous and non-air porous materials.

[0060] It will be apparent to those skilled in the art that variations and modifications of the present invention can be made without departing from the scope of the invention. For example, the shape, size, and material selection for the various components of the blood-drawing device may be changed without departing from the intended scope of the invention as defined by the appended claims. It is further appreciated that forming one or more elements of the apparatus embodiments of the present invention integrally as opposed to separately is intended to fall within the scope of the invention as defined by the appended claims.

Claims

1. A flexible sleeve for connection to a blood drawing device, adapted to receive a cannula of said blood drawing device, said sleeve comprising: an open end, a closed end, and an air-permeable and at least partially blood impermeable wall.

2. The sleeve of Claim 1 wherein the wall is at least partially transparent or translucent.

3. The sleeve of Claim 1 or 2 wherein the wall is substantially porous for gas constituents less than about 5 microns in size, and substantially non-porous for liquid constituents about 5 microns or greater in size.

4. The flexible sleeve of any one of Claims 1 to 3 wherein the wall comprises:

   one or more openings provided in material non-porous to air; and
   an air porous collar covering the one or more openings in the non-porous to air material.

5. The flexible sleeve of any one of Claims 1 to 4 wherein the wall comprises:

   a tubulation provided in material non-porous to air: and
   an air porous insert disposed in the tubulation.

6. The flexible sleeve of any one of Claims 1 to 5 wherein the wall comprises a mixture of hydrophobic matrix material and hydrophilic porous agent.

7. A method of making an air-permeable at least partially blood impermeable flexible sleeve for connection to a blood drawing device, comprising the steps of:

   providing a hydrophobic matrix material;
   mixing the hydrophobic matrix material with a hydrophilic porous agent;
   forming a flexible sleeve for connection to a blood drawing device from the mixture of hydrophobic matrix material and hydrophilic porous agent; and
   drying the mixture of hydrophilic porous agent sufficiently to render the flexible sleeve air-permeable, wherein the hydrophilic porous agent swells upon contact with aqueous liquid. 1

8. The method of Claim 7 wherein the hydrophilic porous agent is polyacrylamide gel.

9. The method of Claim 7 or 8 further comprising the step of forming at least a portion of the flexible sleeve to be transparent or translucent.

Patentansprüche

1. Flexible Hülse zum Anschluss an ein Blutentnahmegerät, die zum Aufnehmen einer Kanüle des Blutentnahmegeräts angepasst ist, wobei die Hülse Folgendes aufweist:

   ein offenes Ende, ein geschlossenes Ende, und eine luftdurchlässige und mindestens teilweise blutundurchlässige Wand.

2. Hülse nach Anspruch 1, bei der die Wand mindestens teilweise durchsichtig oder lichtdurchlässig ist.

3. Hülse nach Anspruch 1 oder 2, bei der die Wand im Wesentlichen durchlässig für Gasbestandteile einer Größe kleiner als etwa 5 Mikron ist, und in Wesentlichen nicht durchlässig für Flüssigkeitsbestandteile einer Größe von etwa 5 Mikron oder größer ist.

4. Flexible Hülse nach einem der Ansprüche 1 bis 3, bei der die Wand Folgendes aufweist:

   eine oder mehrere Öffnungen, die in luftundurchlässigem Material vorgesehen sind; und
   einen luftdurchlässigen Kragen, der die eine oder mehreren Öffnungen in dem luftundurchlässigen Material bedeckt.

5. Flexible Hülse nach einem der Ansprüche 1 bis 4, bei der die Wand Folgendes aufweist:

   ein röhrenförmiges Element, das in luftundurchlässigem Material vorgesehen ist; und
   einen in dem röhrenförmigen Element angeordneten luftdurchlässigen Einsatz.

6. Flexible Hülse nach einem der Ansprüche 1 bis 5, bei der die Wand eine Mischung aus hydrophobem Matrixmaterial und einem hydrophilen porösen Mittel aufweist.

7. Verfahren zum Herstellen einer luftdurchlässigen, wenigstens teilweise blutundurchlässigen flexiblen Hülse zum Anschluss an ein Blutentnahmegerät, das die folgenden Schritte aufweist:

   Bereitstellen eines hydrophoben Matrixmaterials;
   Mischen des hydrophoben Matrixmaterials mit einem hydrophilen porösen Mittel;
   Bilden einer flexiblen Hülse zum Anschluss an ein Blutentnahmegerät aus einer Mischung aus hydrophobem Matrixmaterial und einem hydrophilen porösen Mittel; und
   Trocknen der Mischung aus hydrophilem porösem Mittel in ausreichender Weise, um die flexible Hülse luftdurchlässig zu gestalten, wobei

das hydrophile poröse Mittel bei Kontakt mit wässriger Flüssigkeit aufquillt.

8. Verfahren nach Anspruch 7, bei dem das hydrophile poröse Mittel Polyacrylamidgel darstellt.

9. Verfahren nach Anspruch 7 oder 8, das weiter den Schritt aufweist, mindestens einen Teil der flexiblen Hülse durchsichtig oder lichtdurchlässig auszubilden.

Revendications

1. Manchon souple à des fins de raccordement à un dispositif de prélèvement de sang, adapté à des fins de réception d'une canule dudit dispositif de prélèvement de sang, ledit manchon comportant : une extrémité ouverte, une extrémité fermée, et une paroi perméable à l'air et au moins partiellement imperméable au sang.

2. Manchon selon la revendication 1, dans lequel la paroi est au moins partiellement transparente ou translucide.

3. Manchon selon la revendication 1 ou la revendication 2, dans lequel la paroi est sensiblement poreuse pour les constituants gazeux inférieurs à environ 5 microns en taille, et sensiblement non poreuse pour les constituants liquides d'environ 5 microns ou plus en taille.

4. Manchon souple selon l'une quelconque des revendications 1 à 3, dans lequel la paroi comporte :

une ou plusieurs ouvertures mises en oeuvre dans un matériau non poreux à l'air ; et
une collerette poreuse à l'air recouvrant lesdites une ou plusieurs ouvertures mises en oeuvre dans le matériau non poreux à l'air.

5. Manchon souple selon l'une quelconque des revendications 1 à 4, dans lequel la paroi comporte :

une tubulure mise en oeuvre dans un matériau non poreux à l'air; et
une garniture intérieure poreuse à l'air disposée dans la tubulure.

6. Manchon souple selon l'une quelconque des revendications 1 à 5, dans lequel la paroi comporte un mélange constitué d'un matériau à matrice hydrophobe et d'un agent poreux hydrophile.

7. Procédé permettant de réaliser un manchon souple perméable à l'air au moins partiellement imperméable au sang à des fins de raccordement à un dispositif de prélèvement de sang, comportant les étapes consistant à :

mettre en oeuvre un matériau à matrice hydrophobe ;
mélanger le matériau à matrice hydrophobe à un agent poreux hydrophile ;
former un manchon souple à des fins de raccordement à un dispositif de prélèvement de sang à partir du mélange constitué d'un matériau à matrice hydrophobe et d'un agent poreux hydrophile ; et
sécher suffisamment le mélange d'agent poreux hydrophile pour rendre le manchon souple perméable à l'air, dans lequel l'agent poreux hydrophile gonfle suite à tout contact avec un liquide aqueux.

8. Procédé selon la revendication 7, dans lequel l'agent poreux hydrophile est du gel de polyacrylamide.

9. Procédé selon la revendication 7 ou la revendication 8, comportant par ailleurs l'étape consistant à former au moins une partie du manchon souple pour qu'elle soit transparente ou translucide.

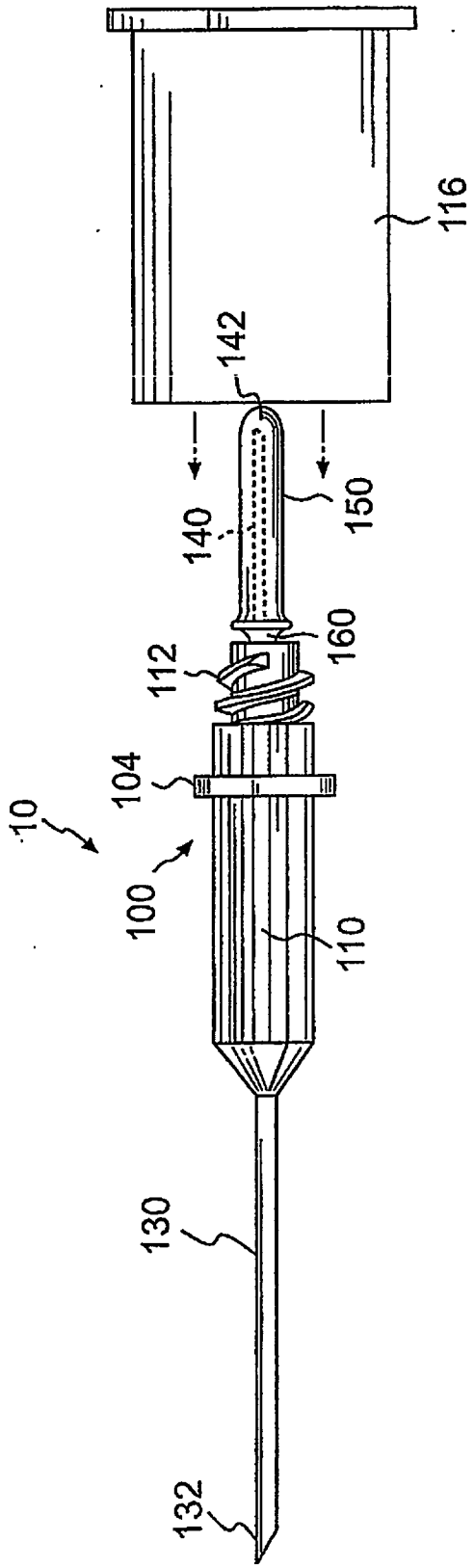
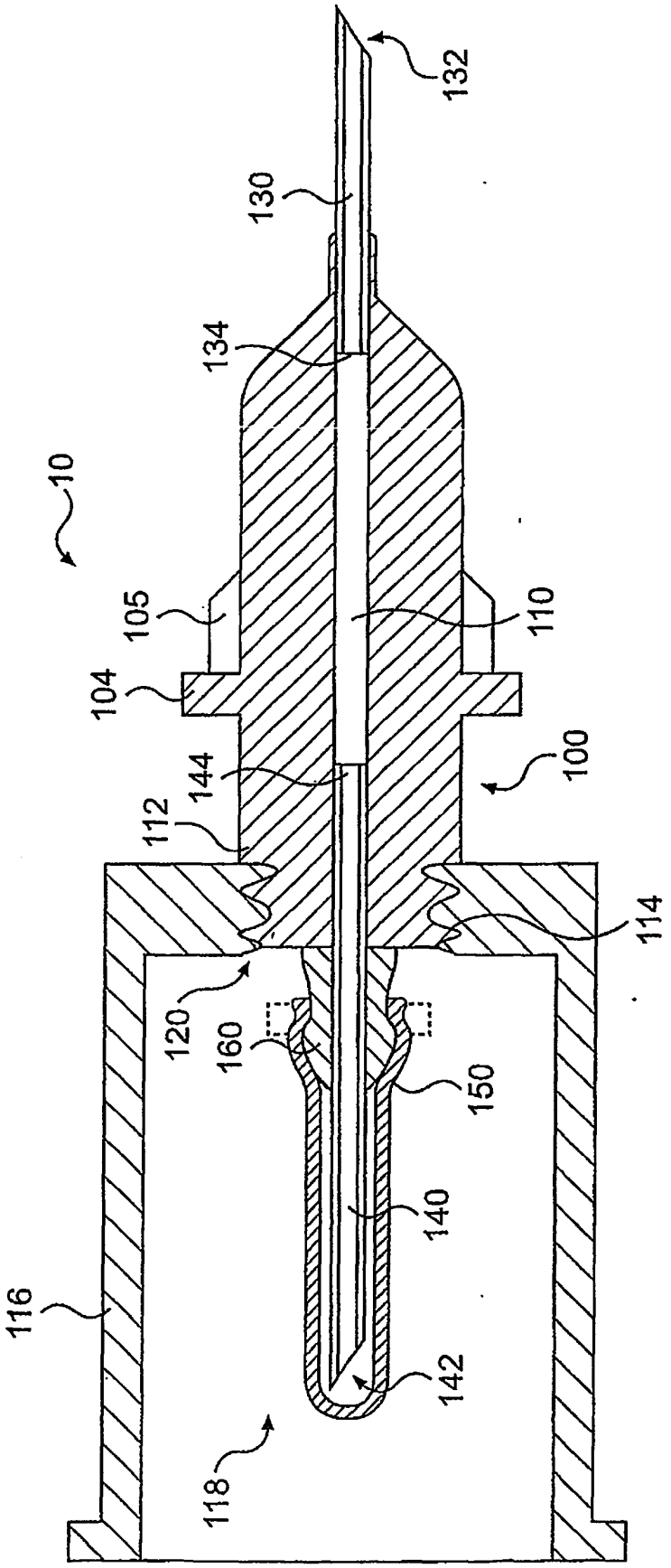


FIG. 1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130
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110
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144
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112
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142
118

FIG. 2

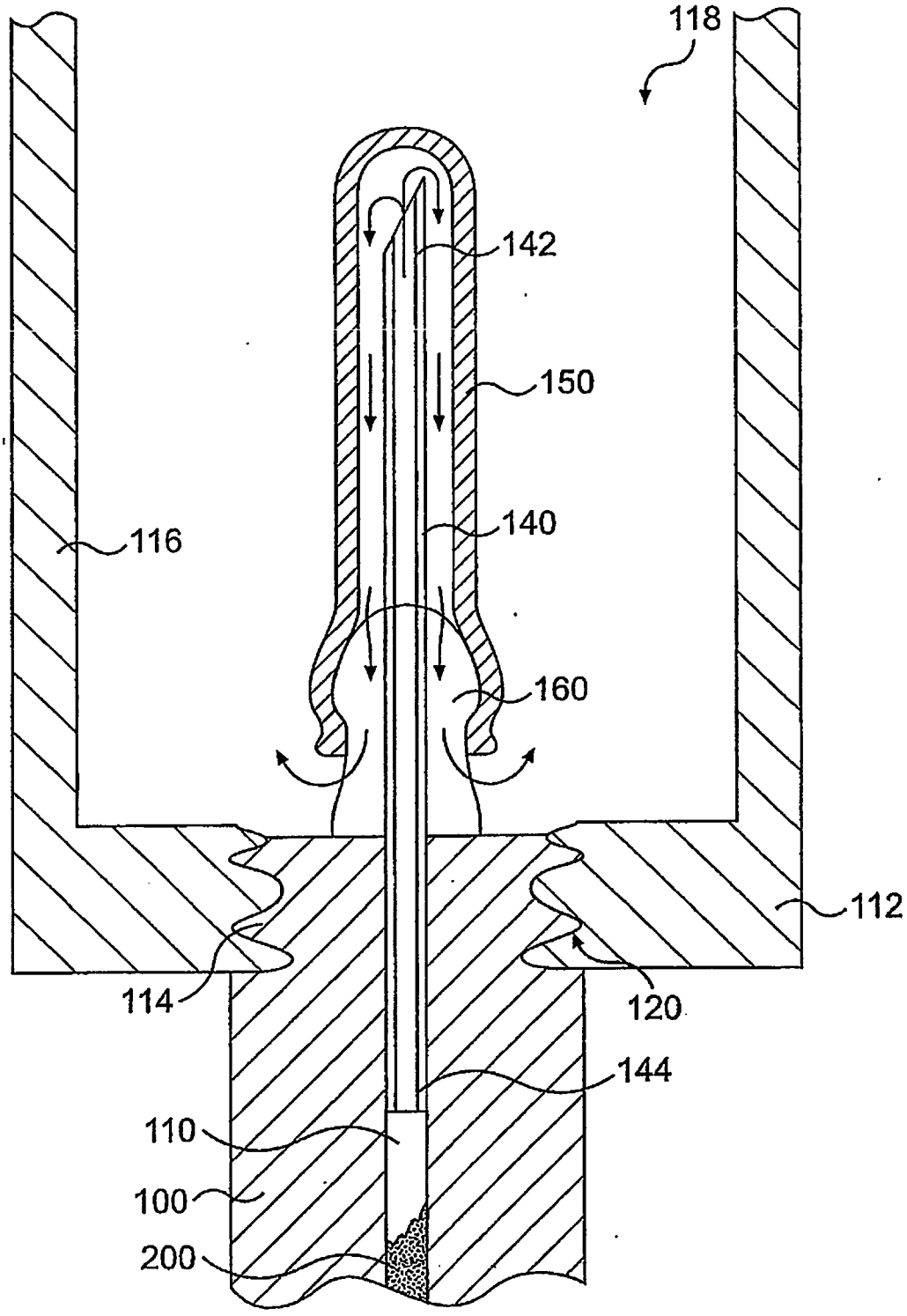

FIG. 3

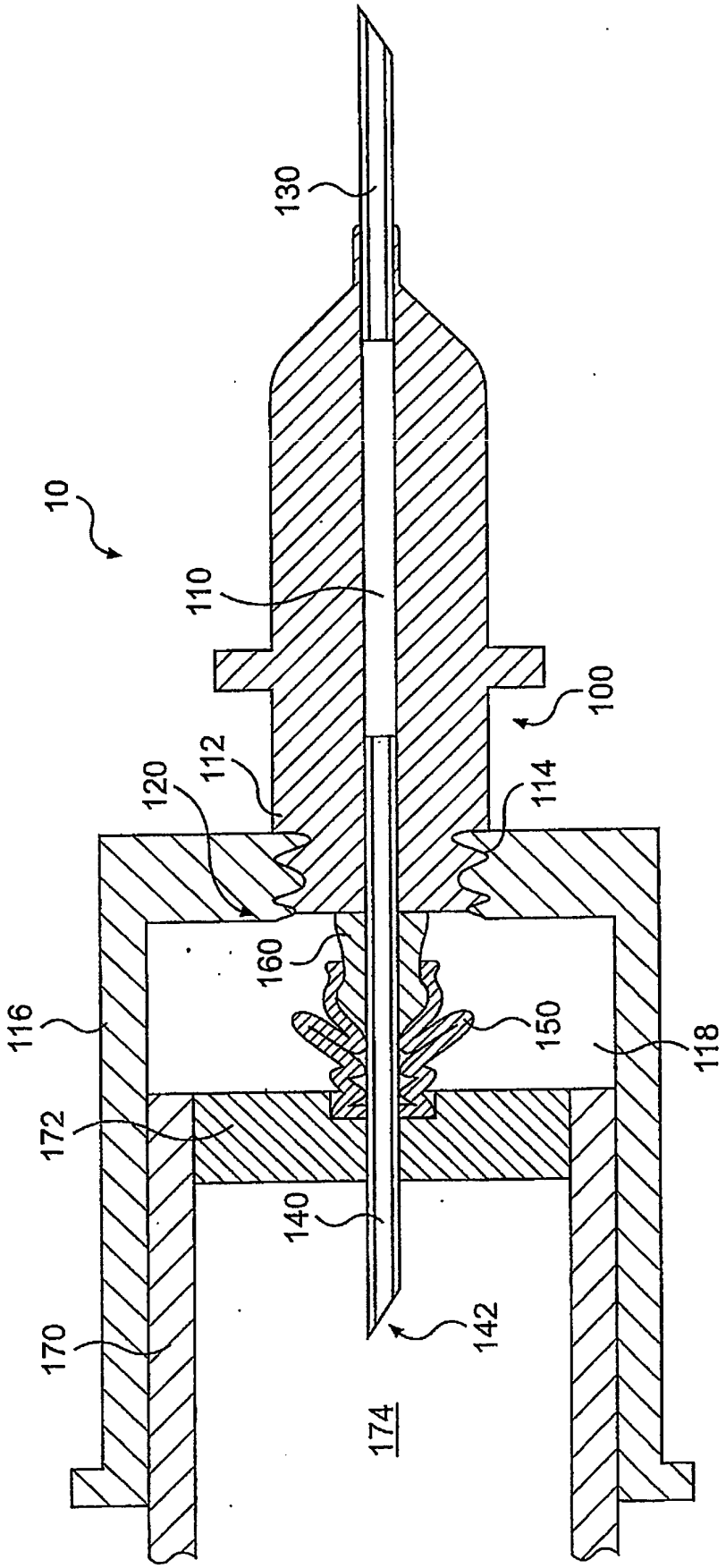

FIG. 4

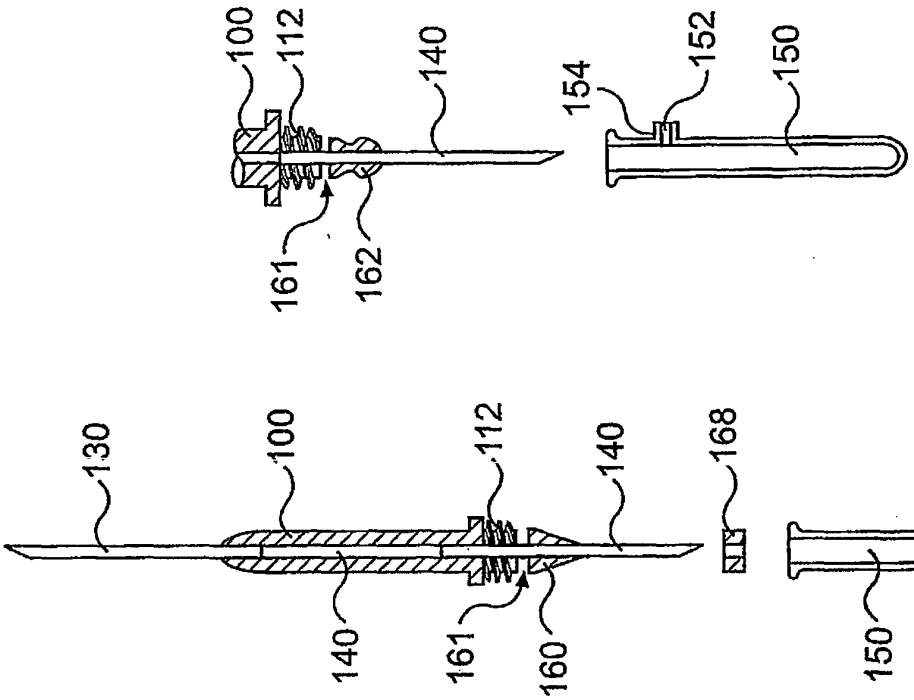

FIG. 7

FIG. 6

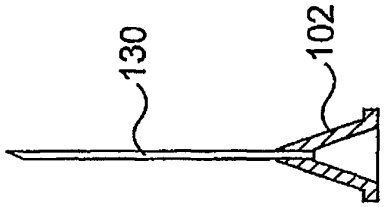

FIG. 5B

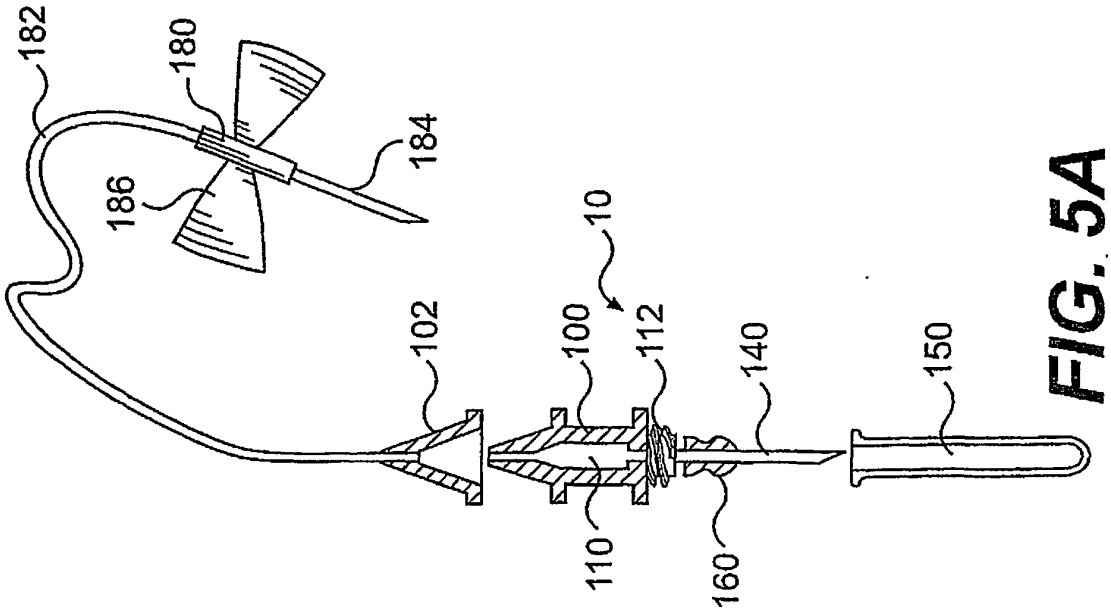

FIG. 5A

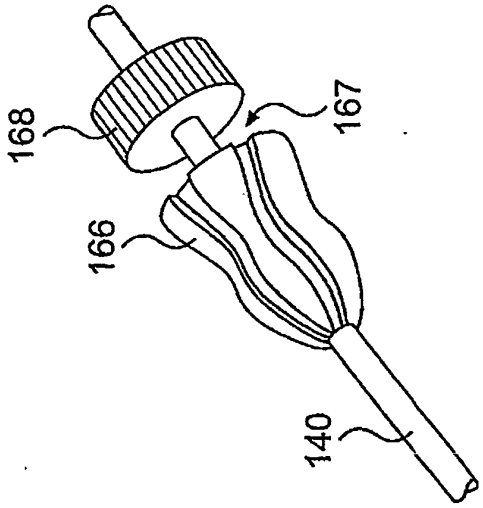

FIG. 10

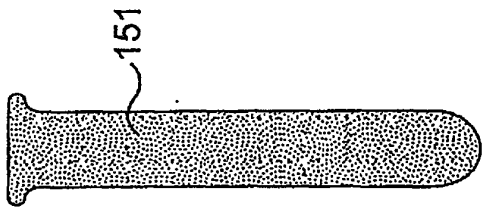

FIG. 9

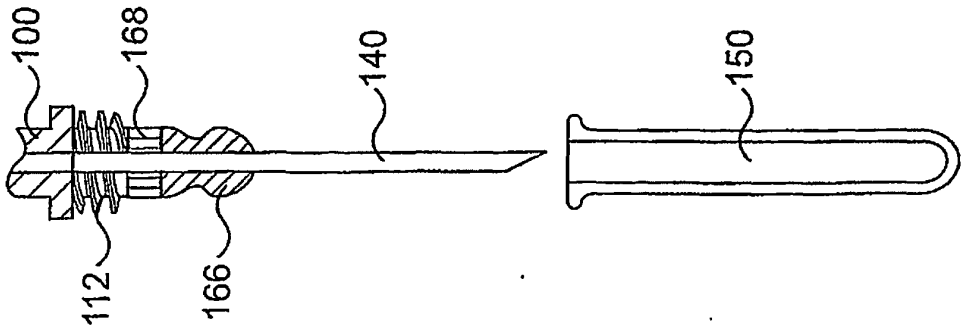

FIG. 8

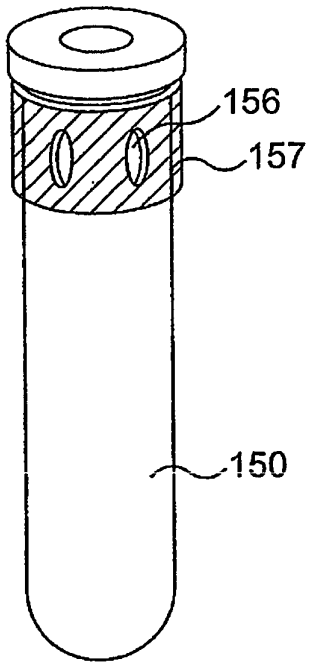

FIG. 11

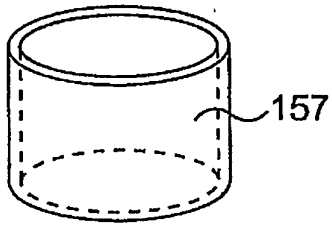

FIG. 12

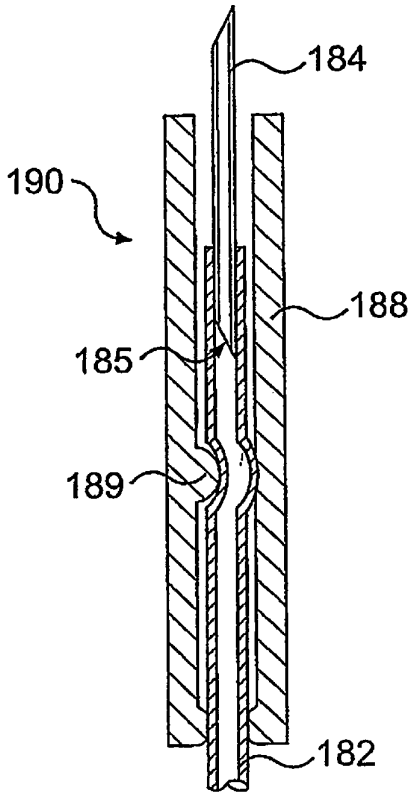

FIG. 13

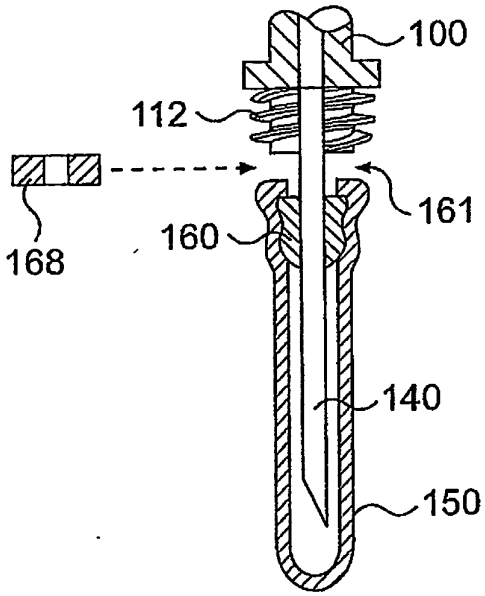

FIG. 14

REFERENCES CITED IN THE DESCRIPTION

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专利名称(译)	抽血装置		
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申请号	EP2010155396	申请日	2005-04-15
申请(专利权)人(译)	清晰的视野病人安全产品有限责任公司		
当前申请(专利权)人(译)	CLEARVIEW患者安全技术有限责任公司		
[标]发明人	BROWN LEROY		
发明人	BROWN, LEROY		
IPC分类号	A61M1/00 A61M5/00 A61M25/00 A61B5/00 B65D81/00 A61B5/145 A61B5/15 H01L21/336		
CPC分类号	A61B5/1545 A61B5/15003 A61B5/150213 A61B5/150221 A61B5/150389 A61B5/150473 A61B5/150503 A61B5/150572 A61B5/150732 A61B5/15074 A61B5/150946		
优先权	10/836190 2004-05-03 US 10/836188 2004-05-03 US		
其他公开文献	EP2196228A1		
外部链接	Espacenet		

摘要(译)

提供一种透气的至少部分不透血的套管，用于从内腔抽取流体的装置，特别是来自血管的血液。该装置可以提供静脉内插管进入内腔的指示。该装置可包括具有外壁和内部流体通道的中心体。该装置可包括鲁尔型适配器，以允许附着I.V.各种长度的输液器（“蝶形针”）和/或连接到现有装置的任何鲁尔型配件。中心体的外壁可以是透明的或半透明的，以允许检测内部流体通道内的流体。前插管可以从中心体的一端延伸，后插管可以从中心体的另一端延伸。前插管和后插管都可以与内部流体通道连通。透气的至少部分不透血的套管可以至少围绕后插管的尖端部分。

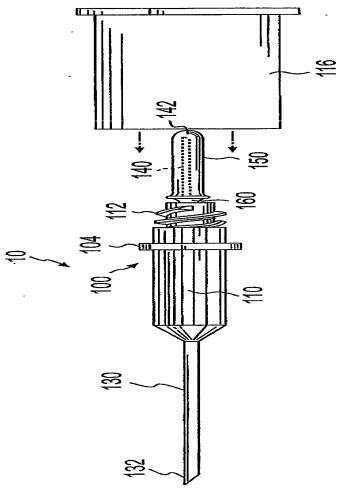

FIG. 1