BLOOD COLLECTION DEVICE WITH NEEDLE CONTAINER MEANS

BACKGROUND OF THE INVENTION

Field of the Invention

[0001] The present invention relates to a blood collection assembly having safety elements for safe and convenient handling. More particularly, the present invention relates to a blood collection assembly which is adapted for retraction of the needle based on forces of gravity.

Description of Related Art

[0002] Disposable medical devices having piercing elements are typically used for administering a medication to or withdrawing a fluid from a patient, such as blood collecting needles, fluid handling needles and assemblies thereof. Current medical practice requires that the fluid containers and needle assemblies used in such systems be inexpensive and readily disposable. Consequently, existing blood collection systems, for example, typically employ some form of durable, reusable holder on which detachable and disposable needles and fluid collection tubes may be mounted. A blood collection system of this nature can be assembled prior to use and then disassembled after use.

[0003] A popular design configuration of conventional blood collection systems includes a double-ended needle assembly, an evacuated collection tube, and a holder for maintaining the needle assembly and the collection tube in fixed relation. The double-ended needle assembly has a bore extending through a cannula and a hub near a central region thereof. The evacuated fluid collection tube includes a puncturable stopper at one end thereof. In this type of blood collection system, the holder typically has a housing at one end thereof for receiving the needle assembly. Likewise, the holder also has a hollow body with an opening at an opposite end thereof for receiving the collection tube. The needle assembly is rigidly received within the housing of the holder such that a first end of the needle, i.e., the patient end, extends forwardly of the holder for puncturing a vein of a patient. The opposite, second end of the needle, i.e., the non-patient end, extends into the hollow body of the holder. Upon assembly of the blood collection system, the needle assembly is inserted into the housing and the collection tube is inserted through the open end of the hollow body until the second end of the needle pierces the puncturable stopper of the collection tube, thereby allowing fluid communication between the interior of the collection tube and the bore which extends through the needle assembly. To draw a blood specimen from a patient using one of these

blood collection systems, the evacuated collection tube is partially inserted into one end of the holder, the first end of the needle is inserted into a patient's vein, and the collection tube is fully inserted into the holder such that blood will be drawn through the bore of the needle assembly and into the fluid collection tube. After drawing the specimen, the collection tube is removed so that the blood contained therein can be analyzed and the needle assembly is detached for disposal.

[0004] In addition to being capable of accommodating blood collection tubes, the holders of some fluid transfer systems are compatible with fluid containers having a fluid to be injected into a patient. Thus, such holders can be used to inject fluid into, as well as draw blood specimens from, a patient.

[0005] Traditionally, needle holders for such blood collection assemblies have been re-usable, with the needle assembly detached from the needle holder after use, and a new needle assembly attached to the needle holder for re-use thereof, often for use with a new patient. For example, U.S. Patent No. 6,306,118 discloses a needle holder assembly for use with a separate double-ended blood collection needle which can be easily engaged to and disengaged from the holder through a trigger arrangement, providing for release of the needle from the holder and into a separate sharps container. Similar needle holders which are adapted for quick release and separation of the needle from the needle holder into a separate container are disclosed in U.S. Patent Nos. 4,942,881; 4,984,580; 5,117,837; 5,143,083; 5,299,687; and 5,755,673. Re-use of a needle holder with different needle assemblies provides the possibility of contamination, such as blood spatter within the needle holder.

[0006] Moreover, in order to reduce the risk of incurring an accidental needle-stick wound, protection of the used needle tip becomes important. With concern about infection and transmission of diseases, methods and devices to enclose the used disposable needle have become very important and in great demand. Arrangements have been designed for protecting used needle tips involving retracting the needle within the needle holder with the entire device including the needle holder and the needle assembly being disposed of together. For example, U.S. Patent No. 5,810,775 to Shaw discloses a collection assembly which provides for retraction of the intravenous needle at the patient end of the assembly, and further discloses a hinged cap at the open end of the housing of the holder. After drawing a specimen into a collection tube, the collection tube is removed, and the hinged cap is closed over the opening of the holder, thereby activating the spring-based needle retraction and blocking access to the second end of the needle at the non-patient end. Activation of the hinged cap and the spring-based retraction mechanism requires substantial manipulation by

the user and cannot be conveniently accomplished with a single hand, as is ideal for typical phlebotomy practice.

[0007] U.S. Patent Application Publication No. 2003/0040717 discloses a retracting needle safety device in which a retraction assembly including a double-ended needle cannula with a patient tip at one end and a non-patient tip at an opposed end is retracted within a tubular body of a needle holder housing after use. The retraction is accomplished through a spring mechanism which biases the retraction assembly into the body of the needle holder housing to contain the needle entirely therein in a manner which is offset from the general axis of the housing.

[0008] U.S. Patent Application Publication No. 2003/0093009 also discloses a needle safety device with a double-ended needle cannula having a patient tip at one end and a non-patient tip at an opposed end, with the needle cannula permanently mounted to a housing for accommodating an evacuated blood collection tube. A spring propels a safety shield to a shielding position covering the patient tip of the needle cannula upon activation, which is accomplished passively when a tube is inserted within the housing by the tube contacting a latch which releases the shield.

[0009] Such prior art retractable needle assemblies and releasable needle assemblies include complex mechanisms for activation, with many relying on spring biasing forces for forced retraction into the attached needle holder housing, or for separation from the housing into a separate container for storing of used needles or sharps.

SUMMARY OF THE INVENTION

[0010] A need exists for a self-contained needle assembly which provides effective protection from both ends of a double-ended needle with simple and efficient retraction of the needle, and which is simple to manufacture and easy to operate.

[0011] A safety blood collection device comprises a holder housing including a generally tubular wall extending between a forward end and an open rearward end to define an interior chamber therein, with the rearward end of the holder housing adapted to receive a sample collection tube therethrough and a needle including a puncture tip extending from the forward end of the holder housing. A retainer co-acts with the holder housing to maintain the needle in a first position with the puncture tip of the needle extending from the forward end of the holder housing. The retainer is adapted for activation so as to release the needle from this first position, thereby permitting the needle to move based on the force of gravity to a second position in which the puncture tip of the needle is contained within the interior chamber of

the holder housing. As such, upright placement of the holder housing upon activation of the retainer will permit the needle to drop within the holder housing, thereby containing the needle cannula therein.

[0012] The needle may comprise a needle hub including a needle cannula, which may be a double-ended needle cannula including a first end having the puncture tip extending from a forward end of the hub, and a second end having a non-patient puncture tip extending from a rearward end of the hub for engagement with a sample collection tube received through the rearward end of the holder housing with the retainer maintaining the needle hub in the first position.

[0013] Desirably, the retainer includes structure for establishing interference engagement for maintaining the needle in the first position with the puncture tip extending from the forward end of the holder housing. The retainer may be adapted to move upon activation thereof, such that movement of the retainer from a first position to a second position causes release of the interference engagement, thereby permitting the needle to move to the second position, i.e., drop within the interior chamber of the holder housing. The assembly may further include structure adapted to close the rearward end of the holder housing when the retainer is in the second position, so as to prevent access to the interior chamber through the rearward end, thereby preventing contact with the needle contained therein.

[0014] A separate hub port may be provided adjacent the forward end of the holder housing for interconnecting the needle hub with the holder housing, such as through a threaded engagement between the needle hub and the hub port. In such an embodiment, the retainer may include structure in interference engagement with the hub port to prevent the needle hub from being released from the forward end of the housing and to maintain the needle hub in the first position with the puncture tip extending from the forward end of the housing. Movement of the retainer to the second position releases the interference engagement between the retainer and the hub port, thereby releasing the hub port and the needle hub and permitting movement of the needle to the second position.

[0015] In one particular embodiment, the retainer comprises a flexible band member including a first portion having a slot which is positioned adjacent the forward end of the holder housing when the flexible band member is in the first position. The needle hub is maintained in a position extending from the forward end of the holder housing in interference engagement with the slot. Movement of the flexible band member toward the second position aligns the needle hub with a second portion of the flexible band member including an opening, which releases the interference engagement, to permit the needle hub to pass

through the opening to the second position in which the puncture tip of the needle cannula is contained within the interior chamber of the holder housing. The flexible band member may further include a third portion, such as a solid flap, adapted to enclose the forward end of the holder housing when the flexible band member is in the second position to prevent re-exposure of the puncture tip of the needle cannula therethrough. Also, the flexible band member may include an opening which is positioned adjacent the rearward end of the holder housing when the flexible band member is in the first position. Desirably, when the flexible band member is moved to the second position, a further flap portion closes the rearward end of the holder housing to prevent access to the interior chamber through the rearward end. Movement of the flexible band member may be accomplished through a finger tab extending through a portion of the housing. Desirably, the flexible band member comprises a continuous band member movable about an interior perimeter of the holder housing. In such an embodiment, a holder insert may be further provided within the holder housing, with the flexible band member sandwiched between the holder insert and the holder housing and adapted for movement therebetween.

[0016] In an alternate embodiment, the retainer comprises a clamping mechanism integrated with the holder housing. In such an embodiment, the clamping mechanism is adapted to move between a first position in which the clamping mechanism secures the needle hub in the first position with the needle cannula extending from the forward end of the holder housing to a second position in which the needle hub is released from the clamping mechanism, thereby permitting the needle hub to move based on the force of gravity to the second position. In this manner, movement of the clamping mechanism to the second position with the holder housing in an upright position permits the needle hub to drop within the holder housing for containment therein. In such an embodiment, the needle hub may further comprise an internal carrier structure extending within the interior chamber of the holder housing. The internal carrier structure prevents movement of the needle hub through the rearward end of the holder housing upon movement of the needle hub to the second position. Such an arrangement is particularly useful with a double-ended needle, in which the needle cannula comprises a first end having a puncture tip extending from a forward end of the needle hub and a second end including a non-patient puncture tip extending from a rearward end of the needle hub. The internal carrier structure desirably extends beyond the length of the non-patient puncture tip within the interior chamber of the holder housing, and includes structure for interference engagement with a portion of the holder housing when the

needle hub is in the second position, thereby preventing the non-patient puncture tip from extending through the rearward opening of the holder housing.

[0017] In a further alternate embodiment, the retainer comprises a ring structure which is rotatable with respect to the holder housing about a longitudinal axis between a first position and a second position. The ring structure includes a tab in interference engagement with the needle hub for maintaining the needle hub in the first position extending from the forward end of the holder housing when the ring structure is in the first position. Rotation of the ring structure to the second position releases the interference engagement between the tab and the needle hub, thereby permitting the needle hub to move based on the force of gravity to the second position in which the puncture tip of the needle cannula is contained within the interior chamber of the holder housing. Desirably, the ring structure extends about an external surface of the holder housing and includes at least one tab extending through the holder housing for interference engagement with the needle hub. The needle hub may include at least one gap extending about a periphery thereof, such that rotation of the ring structure with respect to the holder housing aligns the at least one tab of the ring structure with the at least one gap of the needle hub. In this manner, the interference engagement between the at least one tab and the needle hub is released, thereby permitting the needle hub to move to the second position based on the force of gravity. The needle hub may further include an internal carrier structure extending within the interior chamber of the holder housing to prevent movement of the needle hub through the rearward end of the holder housing upon movement of the needle hub to the second position.

[0018] In yet a further embodiment, a method for containing a needle after use in a blood collection procedure is provided. The method involves providing a blood collection device comprising a holder housing comprising a generally tubular wall extending between a forward end and an open rearward end to define an interior chamber therein, and a needle including a puncture tip maintained in a first position extending from the forward end of the holder housing through a retainer co-acting with the holder housing and including structure in interference engagement with a portion of the needle. In the method, the retainer is activated to release the interference engagement between the retainer and the needle, with the blood collection device positioned such that gravitational forces move the needle to a second position in which the puncture tip of the needle is contained within the interior chamber of the holder housing.

[0019] Desirably, the retainer comprises a flexible band member including a slot adjacent the forward end of the holder housing for establishing interference engagement with the

needle hub and an opening adjacent the slot. Accordingly, activation of the retainer comprises moving the flexible band member with respect to the holder housing to align the needle with the opening adjacent the slot, thereby releasing the interference engagement between the slot and the needle to allow the needle to pass through the opening during the positioning step.

[0020] In a further embodiment, a safety blood collection device comprises a needle extending between a forward end having a patient puncture tip and a rearward end having a non-patient puncture tip; and a needle holder comprising a generally tubular wall extending between a forward end and an open rearward end to define an interior chamber therein. The holder retains the needle in a first position in which the patient puncture tip extends through the forward end of the holder with the non-patient puncture tip maintained within the interior chamber, and is adapted to release the needle from the first position, thereby permitting the needle to move based on the force of gravity to a second position in which the patient puncture tip and the non-patient puncture tip are contained within the interior chamber of the holder. In such an embodiment, the needle holder comprises a retainer adapted to maintain the needle in the first position, with the retainer adapted for activation so as to release the needle from the first position to permit movement to the second position. The needle may be contained and maintained within the interior of the holder after release and movement of the needle from the first position to the second position by structure covering the open rearward end of the needle holder, such as a hinged cover or a rotating flexible band. Alternatively, the needle is contained and maintained within the interior of the holder after release and movement by a carrier structure preventing movement of the needle through the open rearward end of the needle holder upon movement of the needle to the second position.

BRIEF DESCRIPTION OF THE DRAWING(S)

[0021] FIG. 1 is a perspective view of a safety blood collection device in accordance with an embodiment of the invention, shown in use with a blood collection tube.

[0022] FIG. 2 is an exploded perspective view of the safety blood collection device shown in FIG. 1.

[0023] FIG. 3 is a sectional perspective view of the safety blood collection device shown in FIG. 1 in use with the blood collection tube.

[0024] FIG. 4 is a perspective view of a holder housing of the device of FIG. 1.

[0025] FIG. 5 is a perspective view of a retainer in the form of a flexible band of the device of FIG. 1.

[0026] FIG. 6 is a perspective view of a hub port of the device of FIG. 1.

[0027] FIG. 7A is a partial sectional view of the safety blood collection device of FIG. 1 shown in an upright position in the first position with the needle cannula extending from the forward end of the holder housing.

[0028] FIG. 7B is a top down view taken alone line 7B-7B of FIG. 7A.

[0029] FIG. 7C is a bottom up view taken alone line 7C-7C of FIG. 7A.

[0030] FIGS. 8A and 9A are partial sectional views of the safety blood collection device of FIG. 1 shown in an upright position during movement of the retainer from the first position to the second position.

[0031] FIGS. 8B and 9B are top down views taken alone lines 8B-8B and 9B-9B of FIGS. 8A and 9A, respectively.

[0032] FIGS. 8C and 9C are bottom up views taken alone line 8C-8C and 9C-9C of FIGS. 8A and 9A, respectively.

[0033] FIG. 10A is a partial sectional view of the safety blood collection device of FIG. 1 shown in an upright position after the needle cannula has been dropped to the second position contained within the holder housing.

[0034] FIG. 10B is a top down view taken alone line 10B-10B of FIG. 10A.

[0035] FIG. 10C is a bottom up view taken alone line 10C-10C of FIG. 10A.

[0036] FIG. 11 is a perspective view of a safety blood collection device in accordance with an alternate embodiment of the invention.

[0037] FIG. 12 is a perspective view of a rotatable ring structure for use in the embodiment of FIG. 11.

[0038] FIG. 13 is a cross-sectional view of the safety blood collection device of the embodiment of FIG. 11 shown in an upright position in the first position with the needle cannula extending from the forward end of the holder housing.

[0039] FIG. 14 is a top down view taken along line 14-14 of FIG. 13.

[0040] FIG. 15 is a cross-sectional view of the safety blood collection device of the embodiment of FIG. 11 shown in an upright position after the needle cannula has been dropped to the second position contained within the holder housing.

[0041] FIG. 16 is a perspective view of a safety blood collection device in accordance with a further alternate embodiment of the invention.

[0042] FIG. 17 is a cross-sectional view of the safety blood collection device of the embodiment of FIG. 16 shown in an upright position in the first position with the needle cannula extending from the forward end of the holder housing.

[0043] FIG. 18 is a cross-sectional view of the safety blood collection device of the embodiment of FIG. 16 shown in an upright position after the needle cannula has been dropped to the second position contained within the holder housing.

[0044] FIG. 19 is a perspective view of a safety blood collection device in accordance with a further alternate embodiment of the invention.

[0045] FIG. 20 is an enlarged perspective view of the forward end of the blood collection device of FIG. 19.

DESCRIPTION OF THE PREFERRED EMBODIMENT(S)

[0046] The present invention is generally directed to a safety blood collection device, which allows for safe and convenient retraction of a phlebotomy needle, such as a double-ended needle, into a holder device, providing a self-contained device. Generally speaking, retraction of the needle is accomplished by activating a retainer member on the device, which releases the needle assembly, and permits retraction of the needle assembly into the general cavity or interior opening of the holder device based on forces of gravity. After containment in this manner, the device is safe from accidental needle sticks, which may occur during disposal of a needle in a conventional container.

[0047] Referring to the drawings in which like reference characters refer to like parts throughout the several views thereof, FIGS. 1-3 illustrate a blood collection device **10** in accordance with an embodiment of the present invention and its related features. The blood collection device **10** includes a needle holder **12** in combination with a needle, in particular a needle assembly **14** in the form of a double-ended needle, for use in collecting blood samples with a conventional evacuated blood collection tube **16**.

[0048] With particular reference to FIG. 4, holder **12** is defined generally by an outer housing **20** defining a generally hollow tubular wall **22** which includes a first or forward end **24** and a second or rearward end **26**, with tubular wall **22** further defining an interior chamber **28** therein. Tubular wall **22** extends along an axis **A** which generally defines the elongated shape of holder **12**, and is generally tubular in form. Tubular wall **22** may be of any cross-sectional profile, and is desirably a non-circular cross-sectional profile, such as a generally square shaped cross-sectional profile as shown. As such, while housing **20** is described as a tubular structure, housing **20** may define any tubular shape, such as a cylindrical tube, a square tube, or any other tubular shape. Forward end **24** of housing **20** includes a forward opening **30** extending therethrough, while rearward end **26** is generally open-ended through rearward opening **32**, providing housing **20** as a generally hollow tubular outer body having

an interior chamber **28** extending therethrough. Such interior chamber **28** accommodates blood sampling tube **16** during a sampling procedure, as is known in the art. Housing **20** may further include a flange **34** at rearward end **26**. Holder **12** may be comprised of moldable parts which can be mass produced from a variety of materials including, for example, polyethylene, polyvinyl chloride, polystyrene or the like.

[0049] Blood collection device **10** further includes a needle assembly **40** adapted for assembly with holder **12**. Needle assembly **40** generally includes a needle cannula **42** assembled with a needle hub **54**. The needle cannula **42** includes a distal or forward end **44** and an opposing proximal or rearward end **46**, with a lumen **48** extending through needle cannula **42** between the forward end **44** and the rearward end **46**. The forward end **44** of needle cannula **42** may be beveled to define a sharp puncture tip **50**, such as an intravenous puncture tip **50**. The puncture tip **50** is provided for insertion into a patient's blood vessel, such as a vein, and is therefore designed to provide ease of insertion and minimal discomfort during venipuncture. The rearward end **46** includes a non-patient puncture tip **52**, which is provided for puncturing of an evacuated tube, for example, during a blood collection procedure. Needle cannula **42** is desirably constructed of a medical grade metallic material, such as surgical steel or the like.

[0050] Needle assembly **40** further includes a needle hub **54**. Hub **54** is generally tubular or cylindrical in shape, and may be a unitary structure, desirably molded from a resilient thermoplastic material, or may be a multi-component structure. Hub **54** includes a distal or forward end **56** and an opposed proximal or rearward end **58**. The rearward end **58** of hub **54** includes an external portion or structure for mating with needle holder **12**, such as external threads **60**, as will be discussed in more detail herein. Needle assembly **40** may further include an elastomeric sleeve **62** extending about non-patient puncture tip **52** of needle cannula **42**, as is generally known in the art for double-ended blood collection needles. As such, a standard double-ended needle can be used as needle assembly **40**.

[0051] Needle cannula **42** and hub **54** may be separate parts that are preferably fixedly attached and secured through an appropriate medical grade adhesive, for example, epoxy or the like. In particular, the needle cannula **42** may extend through the interior of the hub **54** and be supported by the hub **54**. For this purpose, the hub **54** defines a passageway or opening extending therethrough for receiving and securing the needle cannula **42** therein, such that forward end **44** of needle cannula **42** extends from the forward end **56** of hub **54** and rearward end **46** of needle cannula **42** extends from the rearward end **58** of hub **54**.

[0052] Needle holder **12** includes structure for engagement with hub **54** of needle assembly **40** to maintain needle assembly **40** in fixed relation thereto. Hub **54** is not attached directly to holder **12**, but instead is indirectly connected to holder **12** through a separate member so as to allow for easy release of the needle assembly **40** with respect to the holder **12** for retraction thereof. For example, a hub port **66** may be provided adjacent the forward end **24** of housing **20**. As shown with particular reference to FIG. 6, hub port **66** is desirably a cylindrical member including a main skirt portion **68**, depending from a port flange **70**. Hub port **66** is adapted for interfitting with forward end **24** of housing **20**. For example, outer housing **20** may include a depending skirt **36** extending from the forward end **24** thereof defining forward opening **30**. Main skirt portion **68** may extend partially within depending skirt **36** of holder housing **20**, providing a location for attachment of needle hub **54** of needle assembly **40** to needle holder **12**. The outer diameter of port flange **70** of hub port **66** is slightly greater than the internal diameter of forward opening **30** of outer housing **20**, thereby preventing hub port **66** from passing through forward opening **30** when fully assembled.

[0053] Hub port **66** includes an internal opening **68** for accommodating needle assembly **40** therein, and includes structure to establish mating engagement between needle assembly **40** and housing **20**, such as through a threaded or snap-fit attachment, through permanent bonding, or other connecting manner. For example, hub port **66** may include internal threads **70** provided on an internal surface within internal opening **68** for threaded engagement with external threads **60** provided on an external surface of hub **54**. In such an arrangement, hub port **66** may further be provided with structure to prevent rotation of hub port **66** during threading of needle assembly **40** thereto. For example, one or more nubs **72** may be provided about the external surface of hub port **66**, such as a plurality of nubs **72** radially spaced about skirt **68**. Housing **20** may include a corresponding plurality of nubs **38** extending radially within the internal surface of depending skirt **36** at forward opening **30**. Hub port **66** is aligned within depending skirt **36** of housing **20** such that nubs **72** of hub port **66** and nubs **38** within depending skirt **36** provide for interference engagement therebetween, thereby preventing rotative movement of hub port **66**, particularly during threading of needle assembly **40** with hub port **66** during assembly thereof. It is further contemplated that needle hub **54** and/or needle cannula **52** may be integrally formed directly with hub port **66**.

[0054] Blood collection device **10** further includes a mechanism to maintain needle assembly **40** in a first position extending from the forward end **24** of housing **20**, ready for use. For example, housing **20** may include structure integrally formed therewith or attached thereto for releasably maintaining needle assembly **40** in such a first position. This may be

accomplished in a manner as shown in FIGS. 1-3 through a retainer member **80** co-acting with housing **20**. Retainer **80** provides a mechanism for activation to release needle assembly **40** from this first position, thereby permitting the needle assembly **40** to move to a second position in which the intravenous puncture tip **50** is contained within interior chamber **28** of housing **20**, as will be discussed in more detail herein.

[0055] As depicted in FIGS. 1-3, retainer **80** may be in the form of a flexible band member **82** extending within outer housing **20**. Flexible band member **82** is desirably a generally flat band structure, and in one embodiment is integrally formed or otherwise affixed into an integral loop structure to form a continuous band member, as shown in FIG. 5.

[0056] Flexible band member **82** is desirably maintained within interior chamber **28** of outer housing **20** in a manner so as to be movable about an internal surface of outer housing **20**. For example, an inner housing insert **110** may be provided within the interior chamber **28** of outer housing **20**, with flexible band member **82** sandwiched between outer housing **20** and inner housing insert **110**. Inner housing insert **110** includes a general profile and shape so as to be readily received within the interior chamber **28** of outer housing **20**. Desirably, inner housing insert **110** defines a generally hollow tubular wall **112** which includes a first or forward end **114** and a second or rearward end **116** with tubular wall **112** further defining an interior chamber **118** therein. As with outer housing **20**, tubular wall **112** of inner housing insert **110** is desirably of a non-circular cross-sectional profile, such as a square shaped cross-sectional profile as shown. Forward end **114** of inner housing insert **110** includes a forward opening **120** extending therethrough, while rearward end **116** is generally open-ended through rearward opening **122**, providing access into interior chamber **118**. Such interior chamber **118** accommodates blood sampling tube **16** during a sampling procedure, as is known in the art. Inner housing insert **110** is desirably comprised of moldable parts similar in material as that of outer housing **20**.

[0057] As noted, inner housing insert **110** provides a mechanism for maintaining flexible band member **82** within interior chamber **28** of outer housing **20**. Accordingly, inner housing insert **110** and outer hosing **20** desirably include structure for locking engagement therebetween. For example, inner housing insert **110** may include one or more fingers **124** extending from the outer surface thereof, such as at rearward end **116**, for interlocking engagement with one or more corresponding recesses or openings **124** through tubular wall **22** of outer housing **20**. Such interlocking engagement provides a mechanism for a snap-fit locking engagement, thereby fixing flexible band member **82** sandwiched between inner housing insert **110** and outer housing **20**.

[0058] As noted, flexible band member **82** acts as a retainer mechanism to maintain needle assembly **40** in the first position extending from the forward end **24** of housing **20**, and also is adapted to activate so as to release the needle assembly **40** from being held in this forward extending position when desired. This is desirably accomplished by providing flexible band member **82** with a series of slots and openings sized to accommodate different portions of needle assembly **40** therethrough. In particular, as shown in detail in FIG. 5, flexible band member **82** is desirably formed of a continuous band member which includes a first portion **83** including a slot **84** which is sufficiently sized to receive non-patient puncture tip **52** therethrough while preventing hub port **66** from passing therethrough. Slot **84** of first portion **83** extends as a continuous slot, opening into a slot opening **86** at second portion **85** of flexible band member **82**. Slot opening **86** is sufficiently sized in diameter so as to permit hub port **66** to pass therethrough during retraction, as will be discussed in more detail herein in terms of use of the device. A third portion **87** of flexible band member **82** defines a solid band **88**, while a fourth portion **89** defines an opening **90** sized so as to receive tube **16** during a blood sampling procedure. A fifth portion **91** of flexible band **82** defines a solid band **92**.

[0059] Flexible band member **82** is movable about an internal perimeter within interior chamber **28** of outer housing **20** between outer housing **20** and inner housing insert **110**. Such movement may be accomplished by provided a mechanism extending from flexible band member **82** through the tubular wall **22** of outer housing **20**. For example, outer housing **20** may include a slot **100** extending axially through the tubular wall **22** along one side thereof between a forward slot end **102** and a rearward slot end **104**. Flexible band member **82** may include one or more fingers **94** protruding from the outer surface thereof, which are adapted to extend through slot **100**. A separate tab member **96** may be provided for snap-fitting or other type of engagement with fingers **94**. Tab member **96** is adapted for sliding engagement along slot **100** between forward slot end **102** and rearward slot end **104**, with such movement of tab member **96** effecting corresponding movement of flexible band member **82**, as will be discussed in more detail herein.

[0060] Blood collection device **10** is assembled by wrapping or otherwise extending flexible band member **82** about tubular wall **112** of inner housing insert **110**, such that first portion **83** of flexible band member **82** is adjacent forward end **114** of inner housing insert **110** with slot **84** in alignment with forward opening **120**, and with fourth portion **89** of flexible band member **82** adjacent rearward end **116** such that opening **90** of flexible band member **82** is in alignment with rearward opening **120** of inner housing insert **110**. Hub port **66** is inserted within outer housing **20** such that skirt **72** extends into forward opening **30** and

into depending skirt **36**, with nubs **76** on the exterior surface of skirt **72** of hub port **66** in alignment between corresponding nubs **38** within forward opening **30** at depending skirt **36** of outer housing **20**. The forward end **114** of inner housing insert **110**, with flexible band member **82** extending thereabout, may then be inserted through rearward opening **32** and into the interior chamber **28** of outer housing **20**, with fingers **124** of inner housing insert **110** snap-fitting within openings **126** of outer housing **20**. In this manner, hub port **66** is situated within outer housing **20** and wedged between first portion **83** of flexible band member **82** and the forward end **24** of outer housing **20**, with the internal opening **68** of hub port **66** in alignment with slot **84** of flexible band member **82** and in alignment with forward opening **120** of inner housing insert **110**. The outer diameter and/or profile of flange **74** of hub port **66** prevents hub port **66** from extending or passing all the way through forward opening **30** of outer housing **20** in a forward direction, and prevents hub port **66** from extending or passing all the way through slot **84** at first portion **83** of flexible band member **82** in a rearward direction. Further, fingers **94** of flexible band member **82** extend through slot **100** at a side of tubular wall **22** of outer housing **20**. Tab **96** is fitted with fingers **94** in a fixed relationship, at a forward slot end **102** of slot **100**.

[0061] After assembly in this manner, needle assembly **40** can be assembly with holder **12**. For example, the non-patient puncture tip **52** with elastomeric sleeve **62** thereover is passed into forward opening **30** at forward end **24** of outer housing **20**, through slot **84** at first portion **83** of flexible band member **82**, and into the interior chamber **118** within inner housing insert **110**. External threads **60** on the outer surface of hub **54** are threadably engaged with internal threads **70** within internal opening **68** of hub port **66**. During such threading engagement, rotation of hub port **66** is prevented through the interfitting relationship of nubs **76** of hub port **66** and nubs **38** within the forward opening **30** at depending skirt **36** of outer housing **20**. Blood collection device **10** may then be packaged in a conventional sterile package, such as a blister package (not shown) or other packaging methods known to provide such a device as a sterile, ready to use assembly.

[0062] Prior to use, the blood collection device **10** is removed from its package and, if necessary, any protective cover (not shown) extending about the intravenous puncture tip **50** of needle cannula **42** is removed. Blood collection device **10** is thereafter ready for use in a blood collection procedure.

[0063] To use the blood collection device **10**, venipuncture is conducted in a known manner, whereby intravenous puncture tip **50** at forward end **44** of needle cannula **42** is inserted into a target blood vessel of a patient in order to conduct a blood collection

procedure or other procedure as desired. An evacuated tube **16** having a piercable closure **18** is then inserted into rearward opening **32** of outer housing **20**, through opening **90** of flexible band member **82** and through rearward opening **122** of inner housing insert **110** and into interior chamber **118**, such that the piercable closure **18** of the evacuated tube **16** contacts sleeve **62** extending about non-patient puncture tip **52**. When pressure is exerted on the evacuated tube **16** in the axial direction toward the forward end of the device, the piercable closure **18** contacting sleeve **62** causes sleeve **62** to displace, thereby causing non-patient puncture tip **52** to puncture sleeve **66** and, in turn, the piercable closure **18** of the evacuated tube **16**. At such time, the interior of the evacuated tube **16** and lumen **48** of needle cannula **42** are in fluid communication. Since the interior of the evacuated tube **16** is at a negative pressure, blood is drawn from the vein of the patient, through lumen **48** of needle cannula **42** and into the evacuated tube **16**. Multiple samples can be drawn into a number of successive evacuated tubes in this manner.

[0064] When all desired samples have been drawn, evacuated tube **16** is withdrawn from interior chamber **118** and release of the needle assembly **40** from the holder **12** is accomplished. In particular, at this point, blood collection device **10** is at an initial position, or Stage 0, as shown in FIGS. 7A-7C, with needle assembly **40** in a first position with forward end **56** of needle cannula **42** extending from forward end **24** of outer housing **20**. As shown in FIG. 7B, needle assembly **40** is maintained in this first position through port flange **74** of hub port **66** including an outer diameter larger than the slot **84** of first portion **83** of flexible band member **82**, thereby being held in place. As shown in FIG. 7C, opening **90** of fourth portion **89** of flexible band member **82** is in alignment with rearward opening **122** of inner housing insert **110** and rearward opening **30** of outer housing **20** at this initial, stage **0** position. Retainer **80** provided through flexible band member **82** is also in a first position, with tab **92** at the forward slot end **102** of outer housing **20**.

[0065] Release of the needle assembly **40** is accomplished by activation of retainer **80**, that is by movement of flexible band member **82** from the first position shown in FIG. 7A toward a second position, shown through FIGS. 8A-9C and 9A-9C, desirably while blood collection device **10** is in an upright position, although it is also contemplated that activation can be accomplished first followed by later positioning of blood collection device **10** into an upright position. A user contacts tab **96** with a finger and moves tab **96** from the initial position adjacent forward slot end **102** toward rearward slot end **104**, shown in FIG. 8A, representing blood collection device **10a** in a Stage 1 position. During such movement, flexible band member **82** travels between and interior surface of outer housing **20** and about an outer

surface of inner housing insert **110** in a perimetrical loop. As shown in FIG. 8B, during such initial movement, first portion **83** of flexible band member **82** remains adjacent forward opening **30** of outer housing **20**, such that the non-patient puncture tip **52** at rearward end **46** of needle cannula **42** extends through slot **84** and such that port flange **74** remains in interference engagement with the surface of flexible band member **82** surrounding slot **84** at the first portion **83**, preventing rearward movement of needle assembly **40**. As shown in FIG. 8C, during this initial movement fourth portion **89** of flexible band member **82** moves away from rearward openings **32, 122**, and fifth portion **91** of flexible band member **82** extends across rearward openings **32, 122**, such that solid band **92** closes off the rearward openings **32, 122**, preventing access to the interior chamber **118** therein.

[0066] Continued movement of tab **96** toward the rearward slot end **104** results in continued movement of flexible band member **82** between outer housing **20** and inner housing insert **110**, as shown in FIG. 9A with blood collection device at a Stage 2 position. During such continued movement, second portion **85** of flexible band member **82** is moved such that slot opening **86**, which is contiguous with slot **84**, is moved into alignment with forward opening **30** at the forward end **24** of outer housing **20**. Slot opening **86** includes a diameter which is at least slightly larger than the outer diameter of port flange **74** of hub port **66**. Accordingly, as shown in FIG. 9B, such alignment causes hub port **66** to align with slot opening **86**. With blood collection device **10** in an upright position, the force of gravity causes hub port **66**, and needle assembly **40** attached hereto through hub **54**, to move or drop through slot opening **86** and into interior chamber **118** within inner housing insert **110** of holder **12**. Since the overall length of needle assembly **40**, and in particular needle cannula **42** is shorter than holder **12**, non-patient puncture tip **52** is maintained within interior chamber **118** of holder **12** even after intravenous puncture tip **50** falls beyond forward openings **30, 120**. As shown in FIG. 9C, fifth portion **91** of flexible band member **82** extends across rearward openings **32, 122**, at this Stage 2 position with solid band **92** closing off the rearward openings **32, 122** and preventing needle assembly **40** from passing through the rearward openings **32, 122**.

[0067] Further movement of tab **96** to the rearward slot end **104** results in continued movement of flexible band member **82** between outer housing **20** and inner housing insert **110**, as shown in FIG. 10A with blood collection device at a Stage 3 or final position. In this position, third portion **87** of flexible band member **82** is moved to a position such that sold band **88** extending across forward openings **120, 30** of inner housing insert **110** and outer housing **20**, respectively, thereby closing off access to the interior chamber **118** through such

openings, as shown in FIG. 10B. Fifth portion **91** of flexible band member **82** continues to extend across rearward openings **32, 122,** at this Stage 3 position with solid band **92** closing off the rearward openings **32, 122,** as shown in FIG. 9C. Further, flexible band member **82** may be locked into this Stage **3** position to prevent any reverse movement. For example, tab **96** of flexible band member **82** may be locked into detents **106** extending into slot **100,** providing for an interference engagement therewith. Accordingly, flexible band member **82** is locked in position from further movement with respect to holder **12,** and needle assembly **40** is safely contained therein, with intravenous puncture tip **50** and non-patient puncture tip **52** rendered inaccessible. Blood collection device **10** can then be appropriately discarded.

[0068] FIGS. 11-20 depict further embodiments of the present invention, and include many components which are substantially identical to the components of FIGS. 1-10. Accordingly, similar components performing similar functions will be numbered identically to those components of FIGS. 1-10, except that a suffix "a" will be used to identify those similar components in FIGS. 11-15, a suffix "b" will be used to identify those similar components in FIGS. 16-18, and a suffix "c" will be used to identify those similar components in FIGS. 19-20.

[0069] FIGS. 11-15 depict an alternate embodiment of the invention with an alternate retainer structure for effecting activation to release the needle assembly and permit the force of gravity to drop the needle assembly into a safely contained position. In particular, in the embodiment of FIGS. 11-15, the retainer is in the form of a ring structure **130** which extends within the interior chamber **28a** of outer housing **20a** which defines holder **12a.** More particularly, blood collection device **10a** includes holder **12a** in the form of outer housing **20a** including tubular wall **22a** extending between forward end **24a** and rearward end **26a** to define interior chamber **28a** therebetween. Forward opening **30a** extends through forward end **24a,** and rearward end **26a** is generally open-ended defining rearward opening **32a.** Flange **34a** may circumscribe at least a portion of the rearward end **26a,** while depending skirt **36a** may extend about forward opening **30a** at forward end **24a.**

[0070] Blood collection device **10a** also includes needle assembly **40a** adapted for assembly with holder **12a.** Needle assembly **40a** includes a needle cannula **42a** extending between a forward end **44a** having an intravenous puncture tip **50a** and a rearward end **46a** having a non-patient puncture tip **52a,** and with a lumen **48a** extending therethrough. Needle cannula **42a** is assembled with a needle hub **54a,** including a forward end **56a** and an opposed rearward end **58a.** The rearward end **58a** of hub **54a** includes an external portion or structure for mating with a portion of needle holder **12a,** such as external threads **60a.** Needle

assembly **40a** may further include an elastomeric sleeve **62a** extending about non-patient puncture tip **52a** of needle cannula **42a**.

[0071] In the embodiment described in FIGS. 11-15, the retainer takes the form of a rotating ring structure **130**, as opposed to the flexible band member (**82**) described with reference to FIGS. 1-10. As such, the blood collection device **10a** of FIGS. 11-15 does not include any corresponding inner housing insert **110** to maintain such a flexible band member in place within the outer housing **20**. Blood collection device **10a**, however, does include an internal carrier structure **140** for affixing needle assembly **40a** to holder **12a** and for maintaining and carrying needle assembly **40a** during use, as will be discussed.

[0072] In particular, carrier **140** is positioned within interior chamber **28a** of outer housing **20a**. As shown in FIG. 12, carrier **140** includes a general framework including a forward end **141** and a rearward end **142**. Forward end **141** includes a hub port **143** adapted for interconnection with needle hub **54a** of needle assembly **40a** at forward end **24a**. Such interconnection may be provided, for example, through a threaded or a snap-fit attachment, or through permanent bonding. In one embodiment, hub port **143** may include structure on an internal surface thereof for engagement with an external surface of needle hub **54a**, such as internal threads **147** for threaded engagement with corresponding external threads on the outer surface of needle hub **54a**, as with the embodiment shown in FIGS. 1-10. As such, a standard conventional double-ended needle can be used as needle assembly **40a** in conjunction with carrier **140**. Alternately, needle hub **54a** and/or needle cannula **52a** may be integrally formed with carrier **140**.

[0073] As shown in FIG. 12, carrier **140** further includes at least one, and preferably a plurality of legs **144** extending toward the rearward end **142** of carrier **140** between forward leg surfaces **145** and rearward leg surfaces **146**. Extending between each of these legs **144** are gaps **148**. The external diameter of carrier **140** defined by the outer surfaces of legs **144** is slightly less than the internal diameter of tubular wall **22a** of outer housing **20a**, such that carrier **140** is adapted for sliding movement within interior chamber **28a**. Moreover, the length of legs **144** are preferably equal to or slightly longer than the length of rearward end **46a** of needle cannula **42a** extending between non-patient puncture tip **52a** and the rearward end **58a** of needle hub **54a**. In this manner, non-patient puncture tip **52a** does not extend beyond legs **144** when needle assembly **40a** is assembled with carrier **140**.

[0074] Carrier **140** is adapted for movement within interior opening **28a** of outer housing **20a** of holder **12a** from a first position in which intravenous puncture tip **50a** extends from forward end **24a** of outer housing **20a** through forward opening **30a**, to a second position in

which intravenous puncture tip **50a** and non-patient puncture tip **52a** are contained entirely in the interior chamber **28a** within outer housing **20a**. This is accomplished by providing a retainer in the form of ring structure **130**.

[0075] More particularly, ring structure **130** includes an annular ring **132** extending about an external surface of tubular wall **22a** defining outer housing **20a** adjacent rearward end **26a** thereof. Ring structure **130** includes an internal diameter which is desirably slightly greater than the external diameter of tubular wall **22a** defining outer housing **20a**. As shown in FIG. 11, the rearward edge **133** of annular ring **132** desirably rests against a top surface of flange **34a** of outer housing **20a**. Ring structure further includes at least one, and preferably a pair of support arms **134** extending from annular ring **132** toward the forward end **24a** of outer housing **20a**, desirably along an external surface of outer housing **20a**.

[0076] Support arms **134** include fingers **136** at the forward end thereof. Fingers **136** extend through tubular wall **22a** of outer housing **20a** and into interior chamber **28a**. In particular, outer housing **20a** includes housing slots **150** extending through tubular wall **22a** in a direction perpendicular to axis **A**, about the perimeter of tubular wall **22a**. Fingers **136** extend from support arms **134** at the outside outer housing **20a** and through tubular wall **22a** at housing slots **150**. In this manner, fingers **136** of ring structure **130** provide a point of contact for interference engagement with carrier **140**. In particular, with fingers **136** extending through housing slots **150**, rearward leg surfaces **146** of carrier **140** rest upon upper surfaces **138** of fingers **136**, providing for an interfering or abutting engagement therebetween, as shown in FIG. 12. Such engagement maintains needle assembly **40a** in a first position as shown in FIG. 13, with carrier **140** provided within interior chamber **28a** of outer housing **20a**, with intravenous puncture tip **50a** extending from forward end **24a** of outer housing **20a**, and with non-patient puncture tip **52a** contained within interior chamber **28a** of outer housing **20a**. In such a first position, blood collection device **10a** is ready for sampling during a blood collection procedure, as discussed hereinabove.

[0077] After use of blood collection device **10a**, activation of the retainer feature provides for safe containment of the needle assembly **40a**. In particular, ring structure **130** is rotatable with respect to outer housing **20a**, which causes activation of the retainer feature provided through ring structure **130**. As shown in FIG. 14, to effect actuation of blood collection device **10a**, ring structure **130** is rotated such that fingers **136** slide along and through housing slots **150** from a first position in which fingers **136** abut against rearward leg surfaces **146** of carrier **140**, to a second position in which fingers **136** align within gaps **148** between legs **144** (shown at the dotted lines of FIG. 14). At such point, the interfering or abutting engagement

between upper surfaces **138** of fingers **136** and rearward leg surfaces **146** of carrier **140** is released. With blood collection device **10a** in an upright position, the force of gravity causes carrier **140**, and needle assembly **40a** attached thereto, to move or drop into interior chamber **28a** within outer housing **20a** of holder **12a** to a second position as shown in FIG. 15. Since the overall length of needle assembly **40a**, and in particular needle cannula **42a**, is shorter than holder **12a**, non-patient puncture tip **52a** is maintained within interior chamber **28a** of holder **12a** even after intravenous puncture tip **50a** falls beyond forward opening **30a**, as shown in FIG. 15.

[0078] Desirably, alignment of fingers **136** with gaps **148** is accomplished at a first rotative position of ring structure **130** before fingers **136** travel the full distance of housing slots **150**. In this manner, continued rotation of ring structure **130** permits fingers **136** to travel the full distance of housing slots **150**, such that fingers **136** extend into interior chamber **28a** at a position aligning them with the forward surfaces **145** of carrier **140**. In this manner, a reverse travel of carrier **140** through holder **12a** and re-exposure of intravenous puncture tip **50a** is prevented, even if holder **12a** is turned over in an up-ended position. Blood collection device **10a** may further include a mechanism to prevent reverse rotation of ring structure **130** to further prevent re-exposure of intravenous puncture tip **50a**. For example, housing slots **150** may also include a detent **152** for interference engagement with fingers **136** once they pass beyond detent **152**, thereby locking ring structure **130** in the second, rotated position.

[0079] Moreover, carrier **140** is prevented from extending entirely through interior chamber **28a** and falling out of rearward opening **32a**. This may be accomplished through one or more internal abutments **154** providing for abutting engagement with the rearward leg surfaces **146** of carrier **140** when carrier **140** is dropped within interior chamber **28a**. Since the length of legs **144** are equal to or slightly longer than the length of rearward end **46a** of needle cannula **42a**, non-patient puncture tip **52a** does not extend beyond legs **144**. Moreover, with internal abutments **154** spaced from rearward opening **32a**, non-patient puncture tip **52a** is maintained within interior chamber **28a** a sufficient distance to prevent access thereto through rearward opening **32a**. Furthermore, the overall length of needle assembly **40a** including carrier **140** attached or affixed thereto is less than the length of the body portion of outer housing **20a** extending between the internal abutments **154** and the forward end wall defining forward end **24a**. As such, needle assembly **40a** is safely contained entirely within holder **12a**.

[0080] A further embodiment is described with reference to FIGS. 16-18. In particular, in the embodiment depicted in FIGS. 16-18, blood collection device **10b** includes a holder **12b**

defined by an outer housing **20b** including tubular wall **22b** extending between forward end **24b** and rearward end **26b** to define interior chamber **28b** therebetween. Forward opening **30b** extends through forward end **24b**, and rearward end **26b** is generally open-ended defining rearward opening **32b**. Flange **34b** may circumscribe at least a portion of the rearward end **26b**, while depending skirt **36b** may extend about forward opening **30b** at forward end **24b**.

[0081] Blood collection device **10b** also includes needle assembly **40b** adapted for assembly with holder **12b**. Needle assembly **40b** includes a needle cannula **42b** extending between a forward end **44b** having an intravenous puncture tip **50b** and a rearward end **46b** having a non-patient puncture tip **52b**, and with a lumen **48b** extending therethrough. Needle cannula **42b** is assembled with a needle hub **54b**, including a forward end **56b** and an opposed rearward end **58b**. The rearward end **58b** of hub **54b** includes an external portion or structure for mating with a portion of needle holder **12b**, such as external threads **60b**. Needle assembly **40b** may further include an elastomeric sleeve **62b** extending about non-patient puncture tip **52b** of needle cannula **42b**.

[0082] As with the embodiment of FIGS. 11-15, needle assembly **40b** is affixed to holder **12b** through an internal carrier structure **140b** for maintaining and carrying needle assembly **40b** during use. In particular, carrier **140b** is positioned within interior chamber **28b** of outer housing **20b**. As shown in FIG. 17, carrier **140b** includes a forward end **141b** and a rearward end **142b**, with forward end **141b** including a hub port **143b** adapted for interconnection with needle hub **54b** of needle assembly **40b**, such as through internal threads **147b** for threaded engagement with corresponding external threads **60b** on the outer surface of needle hub **54b**. Alternately, needle hub **54b** and/or needle cannula **52b** may be integrally formed with carrier **140b**.

[0083] Carrier **140b** includes a body structure extending toward the rearward end **142b** of carrier **140b** between forward end **141b** and rearward end **142b**. The external diameter of carrier **140b** is slightly less than the internal diameter of tubular wall **22b** of outer housing **20b**, such that carrier **140b** is adapted for sliding movement within interior chamber **28b**. Moreover, the length of carrier **140b** is preferably equal to or slightly longer than the length of rearward end **46b** of needle cannula **42b** extending between non-patient puncture tip **52b** and the rearward end **58b** of needle hub **54b**, such that non-patient puncture tip **52b** does not extend beyond carrier **140b**.

[0084] Carrier **140b** is adapted for movement within interior opening **28b** of outer housing **20b** of holder **12b** from a first position in which intravenous puncture tip **50b** extends from

forward end **24b** of outer housing **20b** through forward opening **30b** to a second position in which intravenous puncture tip **50b** and non-patient puncture tip **52b** are contained entirely within the interior chamber **28b** within outer housing **20b**. This is accomplished by providing a retainer in the form of clamping mechanism **160**.

[0085] Clamping mechanism **160** generally includes a pair of claws **162** adapted to grasp a portion of carrier **140b**, thereby maintaining the needle assembly **40b** in the first position. In particular, carrier **140b** may include grooves **164** for interference engagement with a corresponding surface of claws **162**. To effect release of carrier **140b**, claws **162** are activated, which may involve pressing the claws **162** or tilting of claws **162** out of engagement with grooves **164**. Such movement releases the interference engagement, thereby permitting carrier **140b** with needle assembly **40b** attached thereto to drop within interior chamber **28b** of housing **20b** based on the force of gravity. The rearward end **142b** of carrier **140b** abuts against internal abutments **154b** spaced from rearward opening **32b**, such that non-patient puncture tip **52b** is maintained within interior chamber **28b** a sufficient distance to prevent access thereto through rearward opening **32b**. Furthermore, the overall length of needle assembly **40b** including carrier **140b** attached or affixed thereto is less than the length of the body portion of outer housing **20b** extending between the internal abutments **154b** and the forward end wall defining forward end **24b**. Claws **162** may further be extendable to cover and close off forward opening **30b** at forward end **24b** of housing **20b**, thereby safely containing needle assembly **40b** therein.

[0086] While the clamping mechanism is described herein in terms of a specific embodiment, it is contemplated that it may comprise any mechanism known in the art to hold a conventional double-ended needle assembly to a needle holder for quick release from the holder into a sharps container, with such a mechanism modified for the present invention so as to release the needle assembly into and within the needle holder, as opposed to a conventional technique of releasing it from the needle holder. For example, the clamping mechanism may be modified from that disclosed in U.S. Patent No. 6,306,118 to Crawford et al., the entire disclosure of which is incorporated herein by reference thereto, with such modifications enabling quick and simple release of the needle assembly from a first position with the needle extending from the forward end of the holder for use, to a second position in which the needle drops into the modified holder when in an upright position based on the force of gravity, to be contained therein. Such a modification envisions a departure from the intent of such quick-release assemblies, in that disposal of the entire device with the needle

safely contained within the holder is desired, as opposed to re-use of the holder with a new needle assembly as is the conventional intent of such a quick-release holder.

[0087] FIGS. 19-20 depict a further embodiment in the form of blood collection device **10c**, which includes a holder **12c** defined by an outer housing **20c** extending between forward end **24c** and rearward end **26c** to define an interior chamber therein. Forward opening **30c** extends through forward end **24c**, and rearward end **26c** is generally open-ended defining rearward opening **32c**, circumscribed by flange **34c**. Blood collection device **10c** also includes needle assembly **40c** similar to those described above, adapted for assembly with holder **12c**. Needle assembly **40c** includes a needle cannula **42c** extending between a forward end **44c** having an intravenous puncture tip **50c**, and further includes a rearward end having a non-patient puncture tip and a lumen extending therethrough, as described in connection with the above embodiments. Needle cannula **42c** is assembled with needle hub **54c**, which includes an external portion or structure for mating with a portion of needle holder **12c**. Desirably, needle assembly **40c** is mated with holder **12c** through an internal carrier structure such as those described above in connection with FIGS. 11-18, for maintaining and carrying needle assembly **40c** during use. In particular, needle hub **54c** of needle assembly **40c** may be assembled or integrally formed with a carrier, such as carrier **140b** shown in FIGS. 16-18 positioned within the interior chamber of outer housing **20c**.

[0088] In the embodiment of FIGS. 19-20, holder **12c** includes arm **170** at forward end **24c** thereof. Arm **170** may include a lever structure **172** which extends at least partially across a portion of the forward end **24c** of holder **12c**. Lever **172** further includes a surface **174** which engages a shoulder **176** of hub **54c** in an interference engagement. In this manner, arm **170** maintains hub **54c**, and therefore needle assembly **40c**, in the first position with intravenous puncture tip **50c** extending from the forward end **24c** of housing **12c**.

[0089] Arm **170** may be integrally formed or otherwise attached to outer housing **20c** of holder **12c**. For example, arm **170** may be integrally formed with outer housing **20c** through a living hinge **178**. Living hinge **178** provides arm **170** with the ability to move with respect to outer housing **20c** between a first position in which surface **174** of arm **170** is in interfering engagement with shoulder **176** of hub **54c** to maintain intravenous puncture tip **50c** extending from the forward end **24c** of housing **12c**, and a second position (not shown) in which surface **174** of arm **170** is moved out of engagement with shoulder **176**. Such movement releases the interference engagement, thereby permitting hub **54c** with needle assembly **40c** attached thereto (as well as any carrier element extending within the housing) to drop within the interior chamber of housing **20c** based on the force of gravity. Needle assembly **40c** is

maintained within housing **20c**, such as through a carrier element limiting movement of hub **54c** and needle assembly **40c** as described above. Alternatively or in addition thereto, the rearward opening **32c** of housing **20c** may be closed to prevent access therethrough, thereby safely containing needle assembly **40c** therein.

[0090] While described herein in terms of specific embodiments, the blood collection device of the present invention generally provides an assembly for effecting blood collection during a normal phlebotomy procedure and for safely containing a used needle after such a procedure in a self-contained device. The simple operation of the device relies on the forces of gravity based on the weight of the needle assembly to retract the used needle assembly within the needle holder upon activation of a simple retainer mechanism which releases the needle. In this manner, the user need only activate the device while in an upright position, which allows for gravitational forces to pull the needle within the needle holder, which then acts as a vessel for safe containment of the used needle. Moreover, the needle is safely maintained within the vessel, such as through a retaining mechanism which ensures that the non-patient end of the needle does not extend through the rear opening of the device. Thus, safe containment is effected within its own assembly, without any complex retraction mechanisms to effect a retractive force, such as springs, which can lose their retractive forces over time. The entire assembly after safety containment of the needle within the needle holder can be appropriately discarded in a conventional medical waste container if desired, or in a sharps container, if preferred.

[0091] While satisfied by embodiments in many different forms, specific embodiments are shown in the drawings and described above detail, with the understanding that the present disclosure is to be considered as examplary and is not intended to limit the invention to the embodiments illustrated. Various other embodiments will be apparent to and readily made by those skilled in the art without departing from the scope and spirit of the invention. The scope of the invention will be measured by the appended claims and their equivalents.

THE INVENTION CLAIMED IS:

1. A safety blood collection device comprising:

a holder housing comprising a generally tubular wall extending between a forward end and an open rearward end to define an interior chamber therein, the rearward end of the holder housing adapted to receive a sample collection tube therethrough;

a needle including a puncture tip; and

a retainer co-acting with the holder housing and adapted to maintain the needle in a first position with the puncture tip extending from the forward end of the holder housing, the retainer adapted for activation so as to release the needle, such that the force of gravity acts based on the weight of the needle to move the needle from the first position extending from the forward end of the holder housing to a second position in which the puncture tip is contained within the interior chamber of the holder housing.

2. A safety blood collection device as in claim 1, wherein the retainer comprises structure for establishing interference engagement for maintaining the needle in the first position with the puncture tip extending from the forward end of the holder housing, and wherein the retainer is adapted to move from a first retainer position to a second retainer position upon activation thereof, movement of the retainer from the first retainer position to the second retainer position causing release of the interference engagement, thereby permitting the needle to move to the second position in which the puncture tip is contained within the interior chamber of the holder housing.

3. A safety blood collection device as in claim 2, wherein the needle comprises a needle hub including a needle cannula having the puncture tip at a forward end thereof with the needle hub interconnected with a hub port adjacent the forward end of the holder housing, wherein the retainer structure is in interference engagement with the hub port to retain the hub port from release from the forward end of the housing and to maintain the needle in the first position, and wherein movement of the retainer to the second retainer position releases the interference engagement between the retainer structure and the hub port, thereby permitting the needle to move to the second position.

4. A safety blood collection device as in claim 2, further comprising structure adapted to close the rearward end of the holder housing when the retainer is in the second retainer position to prevent access to the interior chamber through the rearward end.

5. A safety blood collection device as in claim 2, wherein the retainer comprises a flexible band member including a first portion comprising a slot adjacent the forward end of the holder housing when the flexible band member is in the first retainer position, wherein interference engagement with the slot maintains the needle in the first position with the puncture tip extending from the forward end of the holder housing, and wherein movement of the flexible band member toward the second retainer position aligns the needle with a second portion of the flexible band member comprising an opening, thereby releasing the interference engagement and permitting the needle to pass through the opening to the second position in which the puncture tip of the needle is contained within the interior chamber of the holder housing.

6. A safety blood collection device as in claim 5, wherein the flexible band member further includes a third portion adapted to enclose the forward end of the holder housing when the flexible band member is in the second retainer position to prevent re-exposure of the puncture tip of the needle cannula therethrough.

7. A safety blood collection device as in claim 5, wherein the flexible band member includes a finger tab extending through a portion of the housing for causing movement of the flexible band member from the first retainer position to the second retainer position.

8. A safety blood collection device as in claim 5, wherein the flexible band member includes a opening adjacent the rearward end of the holder housing when the flexible band member is in the first retainer position, and wherein the flexible band member further includes a portion adapted to close the rearward end of the holder housing when the flexible band member is in the second retainer position to prevent access to the interior chamber through the rearward end.

9. A safety blood collection device as in claim 5, wherein the flexible band member comprises a continuous band member movable about an interior perimeter of the holder housing.

10. A safety blood collection device as in claim 9, further comprising a holder insert contained within the holder housing, the flexible band member sandwiched between the holder insert and the holder housing for movement therebetween.

11. A safety blood collection device as in claim 1, wherein the needle comprises a needle hub including a needle cannula comprising a first end including the puncture tip extending from a forward end of the hub and a second end including a non-patient puncture tip extending from a rearward end of the hub for engagement with a sample collection tube received through the rearward end of the holder housing with the retainer maintaining the needle in the first position.

12. A safety blood collection device as in claim 1, wherein the retainer comprises a clamping mechanism integrated with the holder housing, the clamping mechanism adapted to move between a first position in which the clamping mechanism secures the needle in the first position with the puncture tip extending from the forward end of the holder housing to a second position in which the needle is released from the clamping mechanism, thereby permitting the needle to move based on the force of gravity to the second position.

13. A safety blood collection device as in claim 12, wherein the clamping mechanism comprises a pair of claws adjacent the forward end of the holder housing and extending externally of the holder housing, the pair of claws being movable from a first clamping position establishing interference engagement for maintaining the needle in the first position to move to a second release position releasing the interference engagement so as to permit the needle to move based on the force of gravity to the second position.

14. A safety blood collection device as in claim 12, further comprising an internal carrier structure extending within the interior chamber of the holder housing and connected with the needle, the internal carrier structure preventing movement of the needle through the rearward end of the holder housing upon movement of the needle to the second position based on the force of gravity.

15. A safety blood collection device as in claim 14, wherein the needle comprises a needle hub including a needle cannula comprising a first end including the puncture tip extending from a forward end of the hub and a second end including a non-patient puncture tip extending from a rearward end of the hub for engagement with a sample collection tube received through the rearward end of the holder housing with the retainer maintaining the needle in the first position, the internal carrier structure extending beyond the length of the non-patient puncture tip within the interior chamber of the holder housing and including structure for interference engagement with a portion of the holder housing when the needle is in the second position, thereby preventing the non-patient puncture tip from extending through the rearward opening of the holder housing.

16. A safety blood collection device as in claim 1, wherein the retainer comprises a ring structure rotatable with respect to the holder housing about a longitudinal axis between a first retainer position and a second retainer position, the ring structure including a finger in interference engagement with the needle for maintaining the needle in the first position extending from the forward end of the holder housing when the ring structure is in the first retainer position, and wherein rotation of the ring structure to the second retainer position releases the interference engagement between the finger and the needle, thereby permitting the needle to move based on the force of gravity to the second position in which the puncture tip of the needle cannula is contained within the interior chamber of the holder housing.

17. A safety blood collection device as in claim 16, wherein the ring structure extends about an external surface of the holder housing and includes at least one finger extending through the holder housing for interference engagement with the needle.

18. A safety blood collection device as in claim 17, wherein the needle comprises a needle hub including a needle cannula having the puncture tip at a forward end thereof, the needle hub including at least one gap extending about a periphery thereof, and wherein rotation of the ring structure with respect to the holder housing aligns the at least one finger of the ring structure with the at least one gap of the needle hub, thereby releasing the interference engagement between the at least one finger of the needle hub and thereby permitting the needle hub to move to the second position based on the force of gravity.

19. A safety blood collection device as in claim 18, wherein the needle hub further comprises an internal carrier structure extending within the interior chamber of the holder housing, the internal carrier structure preventing movement of the needle hub through the rearward end of the holder housing upon movement of the needle hub to the second position based on the force of gravity.

20. A safety blood collection device as in claim 19, wherein the needle cannula comprises a first end including the puncture tip extending from a forward end of the needle hub and a second end including a non-patient puncture tip extending from a rearward end of the needle hub for engagement with a sample collection tube received through the rearward end of the holder housing with the finger of the ring structure maintaining the needle hub in the first position, the internal carrier structure extending beyond the length of the non-patient puncture tip within the interior chamber of the holder housing and including structure for interference engagement with a portion of the holder housing when the needle hub is in the second position, thereby preventing the non-patient puncture tip from extending through the rearward opening of the holder housing.

21. A method for containing a needle after use in a blood collection procedure comprising:

providing a blood collection device comprising a holder housing comprising a generally tubular wall extending between a forward end and an open rearward end to define an interior chamber therein, and a needle maintained in a first position in which a puncture tip of the needle extends from the forward end of the holder housing through a retainer co-acting with the holder housing and including structure providing for interference engagement with the needle;

activating the retainer so as to release the interference engagement between the retainer and the needle; and

positioning the blood collection device such that gravitational forces move the needle to a second position in which the puncture tip is contained within the interior chamber of the holder housing.

22. A method as in claim 21, wherein the retainer comprises a flexible band member including a slot adjacent the forward end of the holder housing for establishing interference engagement with the needle and an opening adjacent the slot, and wherein the

activating step comprises moving the flexible band member with respect to the holder housing to align the needle with the opening adjacent the slot, thereby releasing the interference engagement between the slot and the needle to allow the needle to pass through the opening during the positioning step.

23. A safety blood collection device comprising:

a needle extending between a forward end having a patient puncture tip and a rearward end having a non-patient puncture tip; and

a needle holder comprising a generally tubular wall extending between a forward end and an open rearward end to define an interior chamber therein, the holder retaining the needle in a first position in which the patient puncture tip extends through the forward end of the holder with the non-patient puncture tip maintained within the interior chamber; and adapted to release the needle such that the force of gravity acts based on the weight of the needle to move the needle from the first position to a second position in which the patient puncture tip and the non-patient puncture tip are contained within the interior chamber of the holder.

24. A safety blood collection device as in claim 23, wherein the needle holder comprises a retainer adapted to maintain the needle in the first position, the retainer adapted for activation so as to release the needle from the first position to permit movement to the second position.

25. A safety blood collection device as in claim 23, wherein the needle is contained and maintained within the interior of the holder after release and movement of the needle from the first position to the second position by structure covering the open rearward end of the needle holder.