(12) STANDARD PATENT APPLICATION (11) Application No. AU 2024200620 A1(19) AUSTRALIAN PATENT OFFICE

(54)	Title Sample tube holder and system and method employing same
(51)	International Patent Classification(s) <i>A61B 5/15</i> (2006.01) <i>A61B 5/154</i> (2006.01)
(21)	Application No: 2024200620 (22) Date of Filing: 2024.02.01
(43) (43)	Publication Date:2024.02.29Publication Journal Date:2024.02.29
(62)	Divisional of: 2018227418
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Abstract

A sample tube holder includes an elongated body with an open end suitable for receiving sample vials. A lid is pivotally attached to body and movable to a position over the open end. The lid includes an aperture that is configured to allow a portion of a vascular access needle assembly to extend through the aperture while an access needle and needle protector portion of the assembly are captured and confined within the body to afford added protection against accidental needle sticks.

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Sample Tube Holder And System And Method Employing Same

Related Application

[0001] This application claims priority to and the benefits of U.S. Provisional Patent Application No. 62/465,563, filed March 1, 2017 and U.S. Provisional Patent Application No. 62/512,530, filed May 30, 2017, both of which are hereby also incorporated by reference herein.

Field of the Disclosure

[0002] This patent disclosure relates to a sample tube holder of the general type commonly associated with medical fluid flow circuits for receiving sample tubes or vials, such as Vacutainer ® blood collection tubes or vials, for collecting fluid samples for laboratory testing or evaluation.

[0003] More specifically, the present disclosure concerns a sample tube holder that may be provided individually or as an associated part of a medical fluid flow circuit of the type that may include a vascular needle and connected plastic

- tubing for collecting or processing blood or blood components. For example, it is common to collect whole blood from patients for routine testing or from healthy donors for processing to obtain blood components that may be administered to patients in need of such a blood component as part of a therapeutic procedure. Typically, such a fluid flow circuit includes a donor or patient access device, such
- 20 as a needle, tubing connecting the needle to downstream collection containers or processing devices, such as a centrifuge chamber that separate the blood into component parts, and other associated devices or containers such as filters for removing leukocytes, containers of anticoagulant and/or blood component preservatives and the like.
- 25 **[0004]** The use of needles for drawing blood from a donor or patient has a known risk of post-procedure accidental needle stick for the professional carrying out the particular procedure. Certain precautions have been mandated for covering needles after use to help reduce the risk of such needle sticks, and it is common for access needles to have an associated needle protector that is
- 30 activated or placed over the needle after use so as to protect against accidental sticks.

[0005] In addition to the needles that are used to access a patient's or donor's blood vessel, the sample tube holder that is commonly part of such blood collection systems also has an internal needle. The sample tube holder is typically a cylindrical or barrel shaped device that is generally closed at one end,

with a sampling needle projecting internally into the barrel from the closed end.
The internal sampling needle is usually connected to a port in the closed end that leads directly or indirectly to an access needle or to tubing that leads to an access needle. When it is desired to take a sample, an empty sample tube or vial, typically with an internal vacuum and a puncturable end septum or seal, is
inserted into the sample tube holder until the internal sampling needle pierces the septum. The vacuum in the sample container or vial assists in drawing blood into the sample tube through the internal sampling needle from the access needle or

Sample tube holders of various types and designs may be found in one or more of the following patents, each of which is hereby incorporated by reference in its entirety into the present description: U.S. Patents Nos. 4,932,418; 5,030,209; 5,752,936; 6,540,696; 7,435,231; and 7,479,131.

the associated plastic tubing through which blood or blood components flow.

[0006] It may be further desirable to protect or guard the internal sampling needle of the sample tube holder from accidental needle stick, such as from a

user or other person sticking their finger into the sample tube holder. One design to help prevent such accidental sticks may be found in U.S. Patent No. 6,540,696. It discloses inserting the vascular access needle and needle protector into the open end of the sample tube holder so that the internal needle of the sample tube holder extends into the needle protector. This design calls for particular retaining
 means to be employed in the sample tube holder to engage the needle protector

and help hold the needle protector in the sample tube holder.

[0007] There continues to be a desire for further development of sample tube holders with protective features and the present disclosure is directed to such a sample tube holder, the blood collection or processing system employing such

30 sample tube holder and the method of using it. One non-limiting embodiment is described below for purposes of illustration and disclosure and not for purposes of limitation. Other designs and configurations may incorporate the features of the present disclosure, and the scope of the invention is as defined in the claims now or hereafter filed.

[0008] In accordance with one non-limiting aspect of the present subject matter, a sample tube holder may be provided including a body, open at one end, and including a lid pivotally attached to the body and movable to a closed position at least partially closing the open end, the lid including an aperture configured to capture an access needle and needle protector within the body when the lid is in the closed position and a latch to retain the lid in a closed position.

[0009] The sample tube holder aperture may be sized to capture an access needle and needle protector within the body. The aperture may extend through at least one edge of the lid. More particularly, the sample tube holder lid may be pivotally attached to the body at one side edge and the aperture may extend through a side edge opposite the one side edge. Also, the access needle and needle protector may be part of a needle assembly, and the aperture configured

to allow a portion of the needle assembly to extend through the aperture while capturing or confining the access needle and needle protector within the body.

[0010] A portion of sample tube holder lid bordering the aperture may be raised or elevated above the plane of the rest of the lid or the body open end to provide enlarged internal dimension for receiving, for example, access needle

20 assemblies of differing length. More specifically, the portion of the lid adjacent the entire edge of the aperture may be raised or elevated above the plane of the lid or body open end to provide greater internal space.

[0011] The sample tube holder lid may be pivotally attached to the body by a hinge comprising a passive connecting hinge portion and an active hinge portion.

For example, the active hinge portion may be configured or biased to hold the lid in an open and/or closed position.

[0012] To retain the lid in the closed position, the sample tube holder may comprise a flange at the open end and one of the flange and the lid may include a latching member and the other of the flange and the lid include a latching member

30 engagement. The latching member may comprise a hook and the latching member engagement comprise a hook receiver. At least two latching members may be provided on the lid and the flange may comprise at least two latching

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member engagements to securely hold the lid in a closed position and prevent accidental opening.

[0013] The sample tube holder may include an internal sampling needle within the body and extending from an end of the body opposite the open end.

5 Alternatively, the sample tube holder may be configured to allow user attachment of a sampling needle, for example, via threaded, snap-fit or press-fit arrangement. [0014] The method of using the sample tube holder of claim includes inserting an access needle and needle protector into the open end of the sample tube holder and closing and latching the lid, thereby capturing the access needle and needle protector in the sample tube holder. The presence of the access needle and needle protector in the sample tube holder body helps prevent accidental insertion of a finger into the tube holder body and accidental contact/stick with any sampling needle located in the body.

[0015] The sample tube holder as described herein may be provided separately or as part of a medical fluid flow system including an access needle for accessing the vascular system of a human subject, a needle protector for protecting the access needle from accidental stick after usage, and a sample tube including a body, open at one end, a lid pivotally attached to the body and movable to a closed position at least partially closing the open end, and a fluid

20 port at an end of the body opposite the open end, the port being configured to allow fluid flow connection with the medical fluid flow system, with the lid including an aperture configured to capture the access needle and needle protector within the body when the lid is in the closed position and a latch to retain the lid in a closed position.

25 **[0016]** Such a medical fluid flow system may include a sample tube holder in which the lid aperture is sized to capture or confine the access needle and needle protector within the body. The aperture may extend through at least one edge of the lid, and more particularly, the lid may be pivotally attached to the body at one side edge of the lid and the aperture may extend through a lid side edge opposite

the one side edge where the hinge is located. The aperture may be configured to allow a portion of the needle assembly to extend through the aperture while capturing the access needle and needle protector within the body. The medical fluid flow system sample tube holder may include an internal sampling needle within the body and extending from an end of the body opposite the open end, which is protected against accidental needle sticks when the access needle and needle protector are inserted into the body.

[0017] In the medical fluid flow system, a portion of sample tube holder lid bordering the aperture may be elevated or raised above the plane of the rest of the lid or the plane of the body open end to provide greater distance between a closed lid and the closed end of the body to accommodate needle assemblies of differing length. More particularly, the portion of the lid adjacent to the entire edge
of the aperture may elevated or raised above the plane of the body open end to provide greater interior dimension. In other words, the sample tube holder, whether by itself or as part of a medical fluid flow system, may have a lid aperture that includes a peripheral edge of relatively raised dimension to provide additional interior space and axial length between an end of the body opposite the open end

[0018] The lid of the sample tube holder in the medical fluid flow system may be pivotally attached to the tube holder body by a hinge comprising a passive hinge portion and an active hinge portion. The active hinge portion may be configured to bias the lid to an open and/or closed position.

- 20 **[0019]** To hold the lid closed after the access needle and needle protector are inserted, the medical fluid flow system sample tube holder body may comprise a flange at the open end and one of the flange and the lid may including a latching member, and the other of the flange and the lid may include a latching member engagement. More specifically, the latching member may comprise a hook and
- 25 the engagement may comprise a hook receiver or aperture. The lid may further comprise at least two latching members and the flange comprise at least two latching member engagements to provide more secure connection of the lid in the closed position to avoid accidental opening.

Brief Description of The Drawings

30 **[0020]** Fig. 1 is an exploded plan view, partially in section of a vein or vascular system access needle assembly, including a pre-use needle cover and post-use needle protector.

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[0021] Fig. 2A is a perspective view of the assembled needle assembly of Fig.1 before use.

[0022] Fig. 2B is a perspective view of the needle assembly of Fig. 2A with the needle cover removed, e.g. to prepare the access needle for use.

[0023] Fig. 2C is a perspective view of the needle assembly of Fig. 2B as it would appear after use, with the needle protector or shield advanced to a position covering the access needle to help prevent accidental sticks.

[0024] Fig. 3 is a perspective view of one embodiment a sample tube holder employing various aspects of this disclosure, as explained more fully below. This view shows the sample tube holder with the lid or cover in a fully open position.

[0025] Fig. 4 is a perspective view of the sample tube holder of Fig. 3 taken from a different angle and with the lid or cover closed.

[0026] Fig. 5A is a cross-sectional view of the sample tube holder of Fig. 3 with the lid or cover closed.

15 **[0027]** Fig. 5B is a top view of the sample tube holder of Fig. 5A.

[0028] Fig. 5C is a top view of the sample tube holder similar to Fig. 5B, but with the lid or cover fully open.

[0029] Fig. 5D is an enlarged cross sectional view of the upper part of the sample tube holder of Fig. 5C, taken along line D-D of Fig. 5C, with the lid or cover fully open.

[0030] Fig. 5E is an enlarged cross sectional view taken along line E-E of Fig.5B, showing a latching arrangement for holding the lid or cover closed.

[0031] Fig. 5F is an enlarged cross-sectional view taken along line F-F of Fig.5A.

[0032] Fig. 6A is a view of the underside of an alternative configuration of a sample tube lid or cover that may be used in the sample tube holder of Fig. 3 and having a raised or elevated portion.

[0033] Fig. 6B is a top view of the alternative lid or cover of Fig. 6A.

[0034] Fig. 6C is a partial side view of a sample tube holder employing the 30 alternative lid or cover of Figs. 6A and 6B.

[0035] Fig. 7 is an enlarged partial sectional view of the alternative cover or lid of Fig. 5.

[0036] Figs. 8-10 illustrate a sequence of inserting a used access needle and needle protector of Figs. 1-2 into the sample tube holder of Figs. 3-6.

[0037] Fig. 8 is a perspective view of the sample tube holder with the cover or lid open and ready to receive a used vascular access needle assembly.

[0038] Fig. 9 is a perspective view illustrating insertion of a used access needle, with needle protector in the protecting position over the needle, into the open end of the tube holder.

[0039] Fig. 10 shows further insertion of the access needle assembly into the sample tube holder.

10 **[0040]** Fig. 11 shows the sample tube holder with the cover or lid closed and capturing or confining the used access needle assembly in the sample tube holder for disposal.

[0041] Turning now to a more detailed description of the drawings, Fig. 1 illustrates one example of a vascular access needle arrangement or assembly,

- generally at 18, that may be employed in a blood collection or sampling fluid flow circuit and may be used with the sample tube holder of the present disclosure for post-use protection against accidental sticks. The needle assembly shown in Fig. 1 is solely for purpose of illustration, as other needle assemblies of varying design may also be used.
- 20 **[0042]** As shown in Fig. 1, the needle assembly 18 includes an access needle 20 of stainless steel or other suitable material, pointed at the distal end 22 for transcutaneous insertion, and having an internal fluid flow passageway extending from the distal end to proximal end 24; an elongated needle holder or base 26 fixedly attached at its distal end 28 to the proximal end of needle 20. The
- elongated needle base 26 has an internal fluid flow path for flow of blood or other fluid from the access needle to tubing 102 or to a blood collection or sampling system 104 (see, e.g., Figs. 2A-2C and 9) connected to the other or proximal end 30 of the needle base.

[0043] For pre-use needle protection, an elongated removable cover 32 is
 positioned over the needle for temporary stick protection until the needle must be used. The needle cover may be temporarily attached to and removable from the

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needle base, e.g., frangibly or frictionally connected to the needle base 26, allowing removal when the needle must be used.

[0044] For post-use protection against sticks, a needle protector or protective shield 34 is mounted on the base and configured such that an elongated portion 36 of the needle protector can be advanced by sliding it along the base to a position over the access needle after the procedure is complete. When so advanced, the elongated portion 36 extends over the sharpened distal end 22 of the access needle 20 to protect against accidental needle sticks. The hub portion 38 of the needle protector remains proximate to the proximal end 30 of the needle holder when the elongated portion is advanced distally to cover the needle 20. [0045] Figs 2A-2C illustrate the needle assembly of Fig. 1 in different

operative positions or states. Fig. 2A shows the needle assembly before use, with the removable needle cover 32 covering the needle 20, the needle protector 34 covering most of the needle base 26, and the proximal end 30 of needle base 26

protruding from the hub portion 38 of the needle protector 34, which may be connected as part of a medical fluid flow system such as system 104.

[0046] Fig. 2B shows the needle cover removed from the access needle 20, as it would be in preparation for use of the needle. In Fig. 2c, the post-use position, the needle protector portion 36 is slid into position over the access

20 needle and covering the pointed distal end to protect against post-use accidental sticks.

[0047] Fig. 3 is a perspective view of one embodiment of a sample tube holder, generally at 40, in accordance with the present disclosure. The sample tube holder includes an elongated cylindrical or barrel shaped body 42

substantially closed at one end 44 and open at the other end 46. The body 42 may optionally be referred to as the barrel. The open or proximal end of the body has a flange 48 that is pivotally attached to a lid or cover 50, such as by hinge structure 52 that allows movement of the lid between an open position (allowing sample vial insertion) and a closed position extending over the open end of the 30 body.

[0048] The lid 50 may optionally have one or more arcuate segments 54, which correspond approximately in size or diameter to the curved inner cylindrical

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surface of the body 42 projecting from the underside of the lid for generally closefitting or conforming and guiding receipt into the open end of the body when the lid is closed over the open end of the body.

- [0049] A latch arrangement of any suitable configuration may also be provided for holding the lid closed. As illustrated, for example, a latch may be integrally 5 molded as part of the lid 50 and body 42. More specifically, one of the lid 50 or the body flange 48 may include one or more latching members, such as extending hooks 58, and the other of the lid or the flange may include one or more latching member engagements, such as mating openings 60. In the illustrated embodiment, the hooks 58 project from the underside of the lid 50 and, when the 10 lid is closed, extend into a hook-receiving openings 60 located in flange 48, opposite the hinge 40, providing a secure double locking arrangement. Other latching arrangements providing similarly secure latching may also be used.
- One or more and, for example, all of the body 42, lid or cover 50, hinge [0050] structure 52, and latch arrangement 56 may be integrally and economically 15 molded as one unitary piece from any suitable plastic material, such as polypropylene or polystyrene. As illustrated, the body, lid, hinge structure, arcuate segments 54 and latch hooks 58 and mating openings 60 are all integrally molded as one unitary piece.
- 20 [0051] The lid 50 also has an aperture 62 provided therein. The aperture allows the lid to be closed after a used access needle assembly is inserted into the body 42. The illustrated aperture 62 extends or opens through the outer perimeter or edge of the lid. More particularly, the illustrated aperture 62 opens through the edge of the lid opposite the hinge structure 52 for ease of closing over
- 25 an inserted needle assembly, although the aperture could also be formed so as to extend through the perimeter or edge of the lid at any suitable side or end location that allows closing of the lid after a used needle assembly has been inserted into the body. As may be visualized, and as illustrated later, when a used needle assemble is inserted into the body, a portion of it, such as the a proximal portion
- 30 30 of the needle base 26, hub portion 38 and a segment of connected fluid flow tubing 102, may still protrude from the open end of the body, and the aperture in

the lid allows the lid to close and for the hub portion and/or connected tubing to extend through the aperture.

[0052] The aperture 62 may be formed in the lid 50 in any suitable manner, such as during initial molding or by cutting. In the illustrated arrangement, the aperture is in the form of a substantially rectangular notch that extends from one edge of the lid toward the hinge structure 52.

[0053] The aperture is sized so that the closed lid 50 captures or traps the used access needle 20 and associated needle protector portion 36 within the body 42, thus adding further protection to help avoid accidental needle sticks as well as to reduce the potential for blood spillage from the access needle. More specifically, the aperture is configured so that when the lid is closed it prevents accidental withdrawal of the used needle assembly from the body 42 through the aperture. For example, the aperture is dimensioned so as to be smaller than the portion of the needle assembly (i.e., the combined access needle and needle

protector portion) located within the body, so that it cannot be pulled through the aperture when the lid is closed. As illustrated, the width W of the slot in the lid may be narrower than the proximal end of the needle protector portion 36 that is located in the body. Thus, when the lid 50 is closed over a used needle assembly 18 and latched, the used needle assembly is trapped within the sample tube

- holder body 42. It should be noted that the needle assembly may also be described herein as captured or confined in the tube holder body, and no difference is intended. When so trapped, captured or confined, the used needle assembly is protected against accidental or inadvertent removal from the body of the sample tube holder and the infusion needle 20 is afforded another barrier
- 25 against accidental needle sticks. In other words, when a used needle assembly 18 is inserted into the body 42 of the sample tube holder 40 and the lid 50 closed thereover and latched, the aperture 62 allows the proximal end of the needle assembly to extend from the sample tube holder body through the lid, thus allowing the lid to close, while the access needle and needle protector are
- 30 captured within the sample tube holder body and cannot be withdrawn through the aperture due to the smaller size of the aperture as compared to the needle protector 36. Thus, no special retention means needs to be provided within the

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sample tube holder body to directly engage or retain the needle protector – it is trapped within the sample tube holder body by the closed lid.

[0054] As earlier described, sample tube holders of the type involved here typically have an internal needle that is mounted at the generally closed end of the body 42 and extends upwardly within the holder from the generally closed end 5 toward the open end. This sampling needle may be located within a flexible dust cover that is displaced when a sample vial is inserted into the body 42. This internal needle is connected through a port 64 (Fig. 4) in the closed end of the body to tubing or other apparatus that connects to the fluid source that is to be sampled. The internal needle may be provided at the time the tube holder is 10 manufactured or, alternatively, the sample tube holder body may have a port that employs a threaded connection, snap-fit or press fit connection, with respect to which an internal or sampling needle may be assembled. The port 64 may also extend from the body 42 in the shape of a male luer or luer-lock fitting for 15 connection to other medical devices or components.

[0055] Typically, but not exclusively, the port 64 may be connected to tubing 102 that is part of a medical fluid flow system and leads directly or indirectly to a vascular access needle assembly such as 18. When the user wishes to remove a sample of blood or other fluid, a vacuum-containing vial (sealed at one end by a

- 20 puncturable seal) is inserted into the body until the internal needle punctures the seal and the vacuum in the vial assists in drawing blood or other fluid into the vial. After the sample is taken, the vial may be removed from the sample tube holder body. Although the internal sampling needle of the sample tube holder is recessed in the body 42, when the used needle assembly 18 (with the needle
- 25 protector over the access needle 20) is inserted into the body, such as along side or next to the internal needle, the physical presence of the used needle assembly in the tube holder body helps prevent someone from inserting their finger into the body sufficiently far to contact the sampling needle. When the lid 50 is closed and latched over a used needle assembly 18, the internal sampling needle in the
- 30 sample barrel or body 42 and the access needle are both further protected against someone accidentally or intentionally making contact with the needles.

[0056] Figure 4 shows the sample tube holder 40 of Figure 3 from a different perspective, with the lid 50 closed and latched. In this view the exemplary port 64 may be better seen at the generally closed end of the sample tube holder body 42.

5 [0057] Figs. 5A-5F show additional details of the sample tube holder 40 of Fig.
3. Fig. 5A is a side elevational view of sample tube holder 40, partially in section, with the lid 50 in a closed and latched position. As seen in this version, the distal or generally closed end of the sample tube holder body 42 has the port 64 communicating with a needle mount 66 that is configured, such as by threads, to allow for mounting of an internal needle within the body 42.

[0058] Fig. 5B is a top view of Fig. 5A, looking down onto the closed lid 50. In that figure, the lid aperture 62 is readily visible, as is a portion of the internal needle mount 66 located at distal closed end of the body 42.

- [0059] Fig. 5C is a top view of Fig. 5A, but with the lid 50 in a fully open position. This figure allows for better viewing of the underside of lid 50, the hinge structure 52, arcuate segments 54 and latch hooks 58. Similarly, the flange 48 located at the proximal or open end of tube holder body 42 is plainly visible with the openings 60 for receiving the latch hooks of lid 50 when the lid is closed.
- [0060] Fig. 5D is an enlarged cross-sectional view of the lid 50 and the portion of the tube holder body 42 to which it is attached, in the fully open position, taken along line D-D of Fig. 5C. This enlarged view illustrates the projection of arcuate segment 54 from the underside of lid 50 and also shows one of the openings 60 for a latch hook. Also, various other features of the illustrated hinge structure 52 are visible in this figure. Specifically, one or more connecting flexible hinge
- 25 portions 68 extend between the flange 48 and lid 50 and may be considered to be relatively passive in that they allow the lid to freely pivot about the axis of the flexible hinge portions. In the illustrated hinge structure, there are two flexible hinge portions 68 and, as shown, they flank an active hinge element that is configured to provide a biased hinge type function that tends to hold the lid 50
- 30 open and/or closed. This illustrated active hinge element includes an angled member 70, with two angled legs 72 joined at a vertex 74. The resilience of the plastic material of which the is made and the location of the connection points 76,

78 where the ends of the legs are attached, respectively, to the lid 50 and the body 42 tend to provide a biasing action or force. The connection point 78 with the body 40 is below or offset from the plane of the hinge portions 68, which requires that the angled member 70 flex at the vertex from its normal angular position as the lid opens or closes. This creates a bias, due to the natural resilience of the angled member material, that tends to hold the lid either open or closed depending, respectively, on whether the lid is located in either a more open position or a more closed position relative to an angular position of inflection of the lid where the vertex flexing is greatest.

[0061] Figure 5E is an enlarged cross-sectional view, taken along line E-E of Fig. 5B, showing the lid latching engagement between at least one of the hooks 58 located on lid 50 and one of the hook openings 60 located in flange 48. In the illustrated embodiment each hook is of identical design, as is each of the hook openings, although they could differ if desired. The double locking feature

- provided by two hooks better provides robust resistance to accidental or unintended opening of the lid. As can be seen in Fig. 5E, hook 58 has an enlarged end portion 80 with an inclined surface 82. Due to resilience of the hook material, the inclined surface 82 hooks under and against a mating inclined undercut surface 84 in the hook opening 60 when the lid is closed. Hook 58 is
- 20 attached to lid 50 at a region of relatively thinner material 86 that provides flexibility and resilience to allow the enlarged portion of the hook to pass under and engage the undercut surface 84 of the opening 60

[0062] Figure 5F is an enlarged cross-sectional view, taken along line F-F of Fig. 5A, showing the lid latching engagement between at least one of the hooks 58 located on lid 50 and one of the hook openings 60 located in flange 48. This figure is taken at a viewing angle at 90 degrees relative to the viewing angle

shown in Figure 5E.

[0063] Figs. 6A-6C and Fig. 7 illustrate a modification that may optionally be made to the lid 50 to allow the sample tube holder to accommodate needle

30 assemblies of greater length. More specifically, the lid 50 has a region 90 that extends along at least part of the edge or perimeter of lid aperture 62 and is elevated or raised relative to the plane of the remainder of the lid or the plane of

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the open end of the body 42, against which the lid lies when closed. As can be seen in Fig. 10B, the raised region may extend fully along the entire inner or peripheral edge of the aperture 62, although that may not be necessary in all embodiments.

- [0064] Referring to Fig. 7, a portion of the sample tube holder lid 50 with a raised region 90 is shown in an enlarged view. Also, generally shown there is a diagrammatic example of a needle assembly 92 captured within the sample tube holder when the lid is closed. As can be seen there, the illustrated lid 50 has a portion 90 that extends upwardly from the plane of the remainder of the lid. As
 illustrated, the raised portion extends in a upward arc or curve, terminating at the edge 94 of the lid aperture, although other upwardly extending shapes may be used for the raised region. This raised portion creates a larger (longer) internal space within the sample tube holder between the closed end of the body 42 and the underside of lid 50 when the lid is closed so as to accommodate larger needle
- 15 assemblies such as the needle assembly 92, which is illustrated as having a length that extends above the plane of most of the lid and the plane of the open end of the body. While accommodating such larger needle assemblies, the lid illustrated in Fig. 7 functions like the lid described earlier, i.e., to allow a proximal portion 94 of the needle assembly 92 to extend through the lid aperture while
- 20 capturing or confining the remainder 96 of the needle assembly, including the access needle and elongated needle protector portion, within the body 42 of the sample tube holder to further protect against needle sticks.

[0065] Figs. 8-11 illustrate sequential steps of using a transparent sample tube holder as described above. A transparent sample tube holder allows user

- visualization of the steps. Fig. 8 shows the sample tube holder 40 in a position with the lid 50 open and ready for insertion of the used vascular needle assembly 18. An interior sampling needle 98 (located within dust cover 100) may be seen within the body 42 of the sample tube holder. Fig. 9 illustrates a used needle assembly that is attached to tubing 102 and part of a medical fluid flow system
- 30 104 that includes the sample tube holder 40 and may include additional components such as containers, filters, Y-junctions, additional tubing, etc. The needle assembly (see 36) is being inserted into the open end of the sample tube

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holder body 42, which is preferably carried out by gripping the proximal end of the needle assembly, with fingers away from the access needle. The needle assembly may be inserted into the body such as along side or adacent to or next to the sampling needle, and if desired the needle assembly may include a visual and/or tactile indicator, such as a colored indicator and/or raised bump or rib, to orient the needle assembly relative to the lid 50 and the aperture 62. Fig. 11 shows the resulting arrangement, with the access needle 20, which cannot be seen because it is covered by the needle protector portion 36, inserted inside the sample tube holder body 42 beside the sampling needle 98, with the lid 50 closed and latched, capturing and confining the access needle and needle protector portion within the sample tube holder body. This serves to enhance protection against accidental needle sticks by either the access needle or the sampling needle and helps confine any blood spillage from the access needle or the sampling needle.

<u>Aspects</u>

[0066] The subject matter of the present description may be found, nonexclusively, in various of the aspects set forth below.

[0067] Aspect 1. A sample tube holder including a body, open at one end and including a lid pivotally attached to the body and movable to a closed position at

20 least partially closing the open end, the lid including an aperture configured to capture an access needle and needle protector within the body when the lid is in the closed position and a latch to retain the lid in a closed position.

[0068] Aspect 2. The sample tube holder of aspect 1 in which the aperture is sized to capture an access needle and needle protector within the body.

25 [0069] Aspect 3. The sample tube holder of any one of aspects 1-2 in which the aperture extends through at least one edge of the lid.

[0070] Aspect 4. The sample tube holder of any one of aspects 1-3 in which the lid is pivotally attached to the body at one side edge and the aperture extends through a side edge opposite the one side edge.

30 **[0071]** Aspect 5. The sample tube holder of any one of aspects 1-4 in which the access needle and needle protector are part of a needle assembly and the aperture is configured to allow a portion of the needle assembly to extend through 5

the aperture while capturing the access needle and needle protector within the body.

[0072] Aspect 6. The sample tube holder of any one of aspects 1-5 including an internal sampling needle within the body and extending from an end of the body opposite the open end.

[0073] Aspect 7. The sample tube holder of any one of aspects 1-6 in which a portion of lid bordering the aperture is raised above the plane of the body open end.

[0074] Aspect 8. The sample tube holder of any one of aspects 1-7 in whichthe lid adjacent the entire edge of the aperture is raised above the plane of thebody open end.

[0075] Aspect 9. The sample tube holder of any one of aspects 1-8 in which the lid is pivotally attached to the body by a hinge comprising a connecting hinge portion and an active hinge portion.

15 **[0076]** Aspect 10. The sample tube holder of any one of aspects 1-9 comprising a flange at the open end and one of the flange and the lid including a latching member and the other of the flange and the lid include a latching member engagement.

[0077] Aspect 11. The sample tube holder of any one of aspects 1-10 inwhich the latching member comprises a hook and the engagement comprises a hook receiver.

[0078] Aspect 12. The sample tube holder of any one of aspects 1-10 wherein the lid comprises at least two latching members and the flange comprises at least two latching member engagements.

- 25 **[0079]** Aspect 13. The method of using the sample tube holder of any one of aspects 1-12 and 26 including inserting an access needle and needle protector into the open end of the sample tube holder and closing the lid after such inserting and latching the lid, thereby capturing the access needle and needle protector in the sample tube holder.
- 30 **[0080]** Aspect 14. A medical fluid flow system including an access needle for accessing the vascular system of a human subject, a needle protector for protecting the access needle from accidental stick after usage, and a sample tube

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including a body, open at one end and including a lid pivotally attached to the body and movable to a closed position at least partially closing the open end, a fluid port at an end of the body opposite the open end, the port being configured to allow fluid flow connection with the medical fluid flow system, the lid including an aperture configured to capture an access needle and needle protector within the

5 aperture configured to capture an access needle and needle protector within the body when the lid is in the closed position and a latch to retain the lid in a closed position.

[0081] Aspect 15. The medical fluid flow system of aspects 14 in which the aperture is sized to capture an access needle and needle protector within the body.

[0082] Aspect 16. The medical fluid flow system of any one of aspects 14-15 in which the aperture extends through at least one edge of the lid.

[0083] Aspect 17. The medical fluid flow system of any one of aspects 14-16 in which the lid is pivotally attached to the body at one side edge and the aperture extends through a side edge opposite the one side edge.

[0084] Aspect 18. The medical fluid flow system of any one of aspects 14-17 in which the access needle and needle protector are part of a needle assembly and the aperture is configured to allow a portion of the needle assembly to extend through the aperture while capturing the access needle and needle protector within the body.

20 within the body.

[0085] Aspect 19. The medical fluid flow system of any one of aspects 14-18 including an internal sampling needle within the body and extending from an end of the body opposite the open end.

[0086] Aspect 20. The medical fluid flow system of any one of aspects 14-19in which a portion of lid bordering the aperture is raised above the plane of the body open end.

[0087] Aspect 21. The medical fluid flow system of any one of aspects 14-20 in which the lid adjacent the entire edge of the aperture is raised above the plane of the body open end.

30 **[0088]** Aspect 22. The medical fluid flow system of any one of aspects 14-21 in which the lid is pivotally attached to the body by a hinge comprising a passive hinge portion and an active hinge portion.

[0089] Aspect 23. The medical fluid flow system of any one of aspects 14-22 comprising a flange at the open end and one of the flange and the lid including a latching member and the other of the flange and the lid include a latching member engagement.

5 **[0090]** Aspect 24. The medical fluid flow system of any one of aspects 14-23 in which the latching member comprises a hook and the engagement comprises a hook receiver.

[0091] Aspect 25. The medical fluid flow system of any one of aspects 14-23 wherein the lid comprises at least two latching members and the flange comprises at least two latching member engagements.

[0092] Aspect 26. The sample tube holder of any one of aspects 1-13 in which the aperture includes a peripheral edge of raised dimension to provide additional interior space and axial length between an end of the body opposite the open end and at least a portion of the lid.

- 15 **[0093]** Aspect 27. The medical fluid flow system of any one of aspects 14-25 in which the aperture includes a peripheral edge of raised dimension to provide additional interior space and axial length between an end of the body opposite the open end and at least a portion of the lid.
- [0094] Aspect 28. The method of using the medical fluid flow system of any one of aspects 14-25 and 27 including inserting an access needle and needle protector into the open end of the sample tube holder and closing the lid after such inserting and latching the lid, thereby capturing the access needle and needle protector in the sample tube holder.

[0095] The particular features of this sample tube holder are shown forpurposes of illustration and not limitation, and may be varied without departing from this disclosure.

<u>Claims</u>

1. A sample tube holder including a body, open at one end and including a lid pivotally attached to the body and movable to a closed position at least partially closing the open end, the lid including an aperture configured to capture an access needle and needle protector within the body when the lid is in the closed position and a latch to retain the lid in a closed position.

2. The sample tube holder of claim 1 in which the aperture is sized to capture an access needle and needle protector within the body.

The sample tube holder of claim 1 in which the aperture extends through at
 least one edge of the lid.

4. The sample tube holder of claim 3 in which the lid is pivotally attached to the body at one side edge and the aperture extends through a side edge opposite the one side edge.

5. The sample tube holder of claim 1 in which the access needle and needle protector are part of a needle assembly and the aperture is configured to a allow a portion of the needle assembly to extend through the aperture while capturing the access needle and needle protector within the body.

6. The sample tube holder of claim 1 including an internal sampling needle within the body and extending from an end of the body opposite the open end.

20 7. The sample tube holder of claim 1 in which a portion of lid bordering the aperture is raised above the plane of the body open end.

8. The sample tube holder of claim 7 in which the lid adjacent the entire edge of the aperture is raised above the plane of the body open end.

9. The sample tube holder of claim 1 in which the lid is pivotally attached tothe body by a hinge comprising a connecting hinge portion and an active hinge portion.

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10. The sample tube holder of claim 1 comprising a flange at the open end and one of the flange and the lid including a latching member and the other of the flange and the lid include a latching member engagement.

11. The sample tube holder of claim 10 in which the latching member comprises a hook and the engagement comprises a hook receiver.

12. The sample tube holder of claim 10 wherein the lid comprises at least two latching members and the flange comprises at least two latching member engagements.

13. The method of using the sample tube holder of claim 1 including inserting
 an access needle and needle protector into the open end of the sample tube
 holder and closing the lid after such inserting and latching the lid, thereby
 capturing the access needle and needle protector in the sample tube holder.

14. A medical fluid flow system including an access needle for accessing the vascular system of a human subject, a needle protector for protecting the access needle from accidental stick after usage, and a sample tube including a body, open at one end and including a lid pivotally attached to the body and movable to a closed position at least partially closing the open end, a fluid port at an end of the body opposite the open end, the port being configured to allow fluid flow connection with the medical fluid flow system, the lid including an aperture

20 configured to capture an access needle and needle protector within the body when the lid is in the closed position and a latch to retain the lid in a closed position.

15. The sample tube holder of claim 14 in which the aperture is sized to capture an access needle and needle protector within the body.

25 16. The sample tube holder of claim 14 in which the aperture extends through at least one edge of the lid.

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17. The medical fluid flow system of claim 16 in which the lid is pivotally attached to the body at one side edge and the aperture extends through a side edge opposite the one side edge.

18. The medical fluid flow system of claim 14 in which the access needle and needle protector are part of a needle assembly and the aperture is configured to a allow a portion of the needle assembly to extend through the aperture while capturing the access needle and needle protector within the body.

19. The medical fluid flow system of claim 14 including an internal sampling needle within the body and extending from an end of the body opposite the open end.

20. The medical fluid flow system of claim 14 in which a portion of lid bordering the aperture is raised above the plane of the body open end.

21. The medical fluid flow system of claim 20 in which the lid adjacent the entire edge of the aperture is raised above the plane of the body open end.

15 22. The medical fluid flow system of claim 14 in which the lid is pivotally attached to the body by a hinge comprising a passive hinge portion and an active hinge portion.

23. The medical fluid flow system of claim 14 comprising a flange at the open end and one of the flange and the lid including a latching member and the other of the flange and the lid include a latching member engagement.

24. The medical fluid flow system of claim 23 in which the latching member comprises a hook and the engagement comprises a hook receiver.

25. The medical fluid flow system of claim 23 wherein the lid comprises at least two latching members and the flange comprises at least two latching member engagements.

26. The sample tube holder of claim 1 in which the aperture includes a peripheral edge of raised dimension to provide additional interior space and axial

length between an end of the body opposite the open end and at least a portion of the lid.

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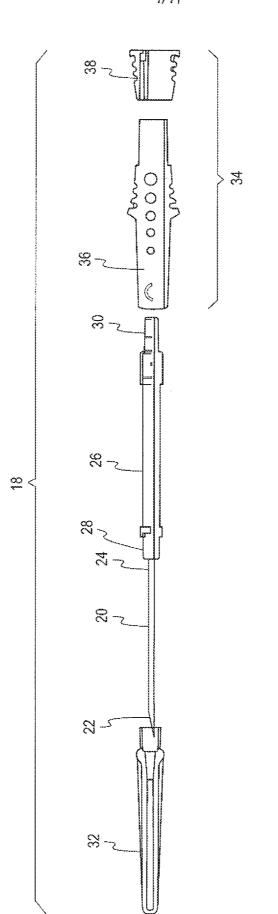
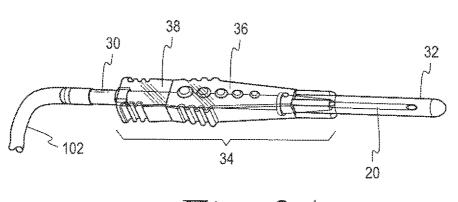
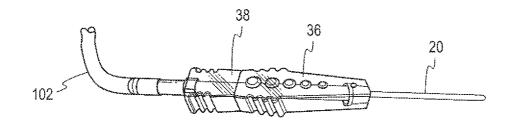


Fig. 1



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Fig. 2A



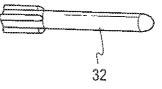


Fig. 2B

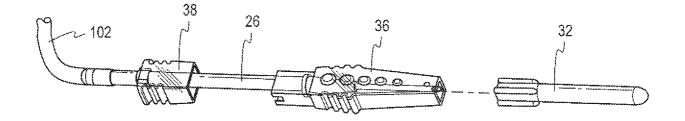


Fig. 2C

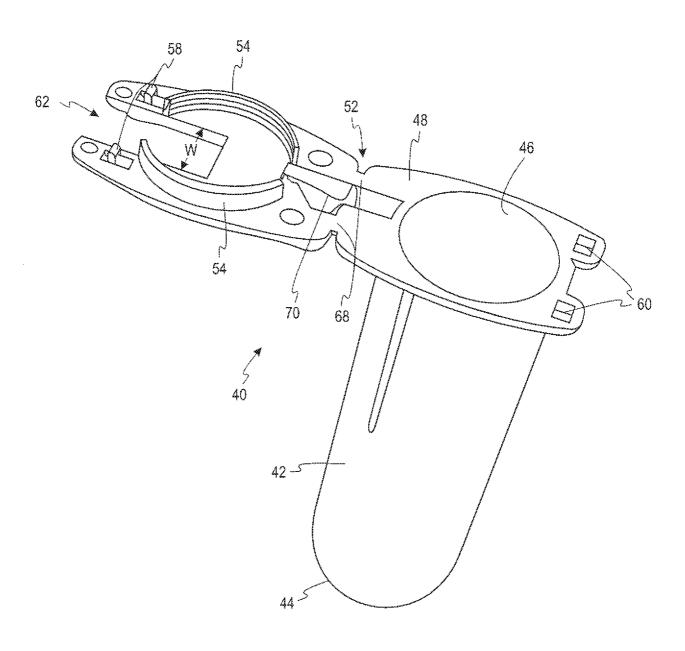


Fig. 3

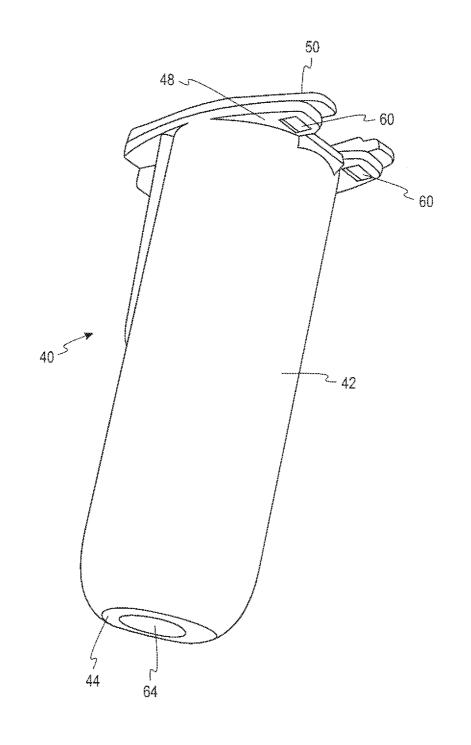


Fig. 4

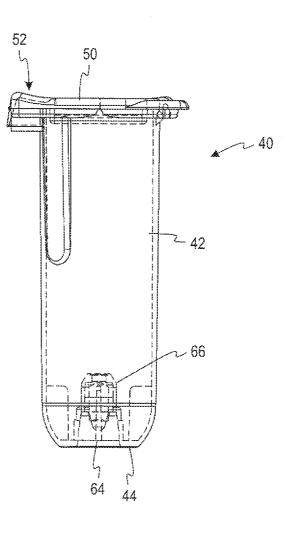


Fig. 5A

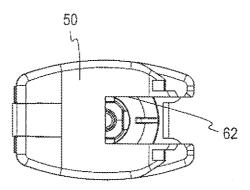
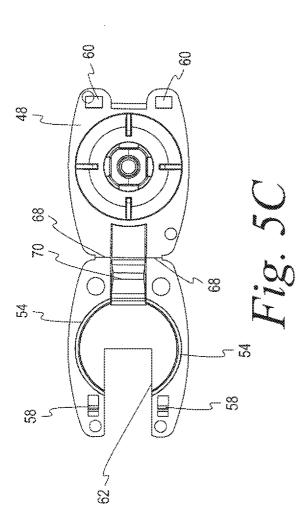
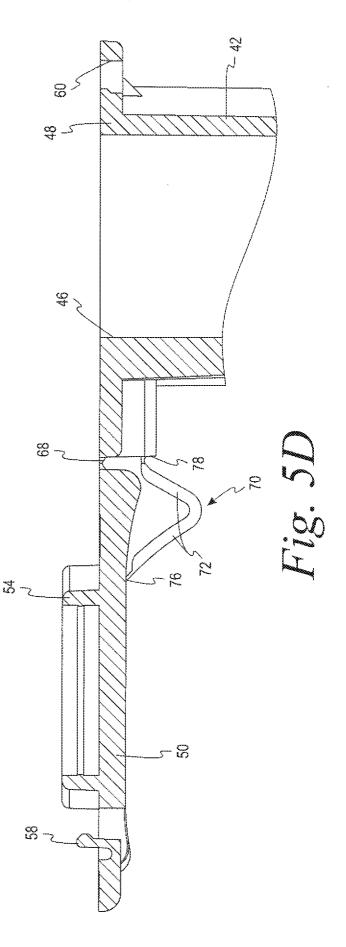


Fig. 5B





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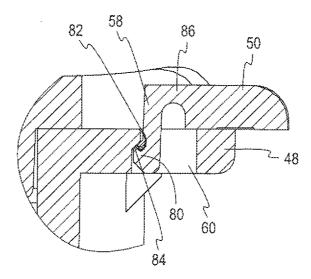


Fig. 5E

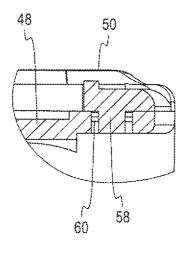
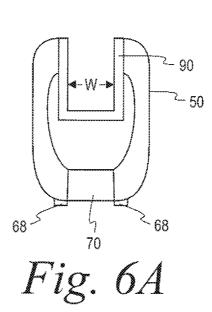
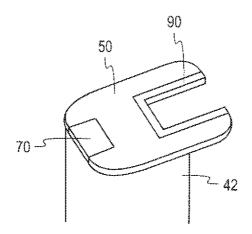
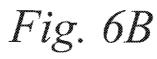


Fig. 5F







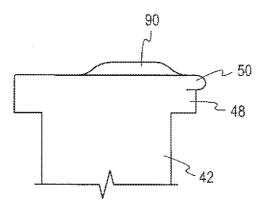


Fig. 6C

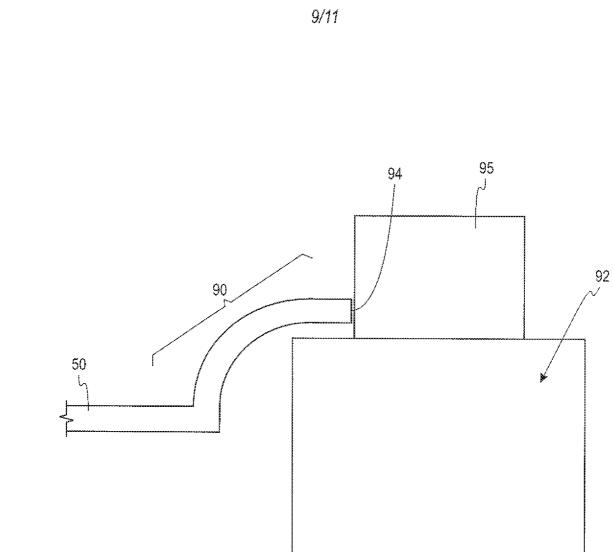


Fig. 7

