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(54) Title: INJECTION PORT PROTECTOR

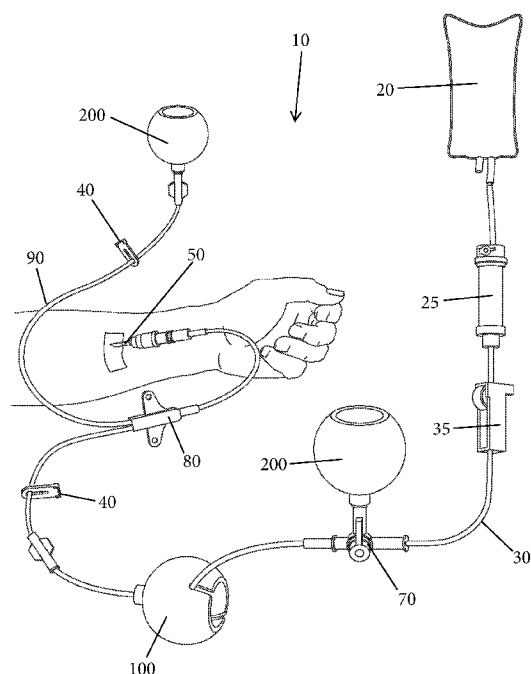


Fig. 1

(57) Abstract: A device is provided for shielding a fluid access port structure that is located along tubing that is part of an intravenous (IV) medication delivery system and is configured to permit injection of a fluid into the tubing. The device includes a body having a hollow interior and a first opening formed therein for receiving the fluid access port structure such that a side wall of the body surrounds and extends above the fluid access port structure. The body also includes a second opening through which a fluid delivery member can be inserted to allow mating between the fluid delivery member and the fluid access port structure for delivering the fluid into the tubing.



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INJECTION PORT PROTECTOR

Technical Field

The present invention generally relates to the field of medical devices and more specifically, to devices (protectors) that shield injection ports that are associated with intravenous medication delivery.

Background

Preventing healthcare associated infections has become a major clinical and economic issue for hospitals and other similar settings. Prior studies have linked microbial contamination of intravenous (IV) ports and stopcocks (from practitioner, patient, and environmental reservoirs) with postoperative infections. It is hypothesized that these microbial contaminants gain entry to the IV tubing, IV catheter, and eventually bloodstream and cause local or distant infection.

Intravenous (IV) injection or infusion of medication means that the medication is sent directly into a person's vein (arm or hand) using a needle or tube. With IV administration, a thin plastic tube called an IV catheter is inserted into the patient's vein. The catheter allows the healthcare provider to give the patient multiple safe doses of medication without needing to poke the patient with a needle each time. IV medication is often used because of the control it provides over a dosage. For instance, in some situations, people must receive medication very quickly. This includes emergencies, such as a heart attack, stroke, or poisoning. In these instances, taking pills or liquids by mouth may not be fast enough to get these drugs into the bloodstream of the patient. IV administration, on the other hand, quickly sends the medication directly into the bloodstream so that the medication can begin working. Other times, medications may need to be given slowly but constantly. IV administration can also be a controlled way to give drugs over time to the patient. Certain drugs can be given by IV administration because if the patient took the medication orally (by mouth), enzymes in the patient's stomach or liver would break them down. This would prevent the drugs from working well when they're finally sent to the patient's bloodstream. Therefore, these drugs are much more effective if sent directly into the patient's bloodstream by IV administration.

Flow paths for gravity feeding IV solutions or infusion pump based IV solutions to a patient are generally equipped with an injection port through which medication (or other fluid) can be delivered directly into the flow line for rapid administration. The injection port typically includes a short piece of tubing that enters the main flow line at an angle and is

capped at its distal end by a needle penetratable membrane. Modern needleless injection ports include a port that has a retractable rubber stopper/septum that gets pushed out of the way when a syringe is attached and then springs back and seals the port when the syringe is removed.

5 Medication can also be delivered into a flow line by use of a stopcock that assists the caretaker in controlling fluid flow through IV delivery systems. As is generally known, a stopcock is an externally operated valve regulating the flow of a liquid or gas through a pipe. Stopcocks that are configured for use with IV delivery systems include at least one injection port that can mate with a fluid delivery device, such as a syringe.

10 In both types of injection ports, there is a risk that contaminants can access the bloodstream through the injection port. One type of contamination is contact contamination in which the injection port contacts contaminated matter, such as skin of a caretaker or patient, bodily fluids, bedsheets, furniture, a floor surface, etc. In such instances, bacteria are transferred from the contaminated surface onto the injection port. It is also possible or less
15 common that the contamination can arise from airborne contaminants.

Various techniques and devices have been shown to decrease contamination, but these are not universally practiced/used or practical. Hand washing helps decrease practitioner contamination, spread of pathogenic microbes to patients and devices (including IV ports and stopcocks) they touch, and ultimately nosocomial infections. However, compliance with
20 frequent handwashing recommendations is often suboptimal due to inconvenience and intolerance. IV stopcocks are typically packaged with protective caps but these are often removed and then never replaced (due to inconvenience of repeated capping and uncapping), leaving the stopcock open to contamination of the fluid path. Alcohol wipes, scrubbing devices, and antimicrobial caps are available to intermittently disinfect injection ports, but
25 they are not consistently utilized because of the time and effort they require. They are particularly inconvenient in the operating room and intensive care settings where frequent and/or rapid medication administration is necessary.

The present invention overcomes the shortcomings of existing technologies and provides barrier devices (protectors) that are configured to prevent IV tubing port and
30 stopcock contamination.

Summary

In accordance with the present invention, barrier devices (protectors) are disclosed that are configured to prevent IV tubing port and stopcock contamination.

In one embodiment, a device is provided for shielding an injection port that is located
5 along tubing that is part of an intravenous (IV) medication delivery system. The device includes a body having a hollow interior and a first opening for receiving a fluid delivery member to allow passage of the fluid delivery member into the hollow interior while the body at least partially encapsulates the injection port. The body further includes a first slot that opens into the first opening and terminates at a closed end and a second slot spaced from the
10 first slot. The second slot also opens into the first opening and terminates at a closed end. The body also includes first and second supports that are formed within the hollow interior and extend transversely thereacross and are formed such that at least a portion of the first slot including the closed end is located therebetween. The first and second supports are configured and positioned for receiving and holding the injection port therebetween, while
15 the first and second slots are configured to allow coupling between the injection port and efferent and afferent limbs of the tubing.

In another embodiment, a device is provided for shielding a stopcock or injection port that is located along tubing that is part of an intravenous (IV) medication delivery system. The device includes a body having a hollow interior and a first opening for receiving a fluid
20 delivery member to allow passage of the fluid delivery member into the hollow interior. The body further includes a second opening that is located opposite the first opening. A connector is disposed within the second opening such that a first connector part at a first end thereof is disposed within the hollow interior and a second connector part at a second end thereof is disposed external to the body. The first connector part is at least partially
25 encapsulated within the body thereby preventing inadvertent contact with the first connector part.

The first connector part is configured to mate with fluid delivery member and the second connector part is configured to mate with a connector associated with the stopcock or injection portarm for establishing a fluid connection between the fluid delivery member and
30 the tubing through the stopcock.

Brief Description of the Drawing Figures

Fig. 1 is a schematic of an exemplary intravenous (IV) medication delivery system having at least one inline injection port and at least one stopcock;

Fig. 2 is a side perspective view of a device according to a first embodiment for shielding an inline injection port to prevent surface contamination thereof;

Fig. 3 is a side and bottom perspective view of the device of Fig. 2;

Fig. 4 is a top and side perspective view of the device of Fig. 2;

5 Fig. 5 is a transverse cross-sectional view of the device of Fig. 2;

Fig. 6 is a top and side perspective view of the device of Fig. 2 with the inline injection port inserted and held therein;

Fig. 7 is a longitudinal cross-sectional view of the device of Fig. 2 with the inline injection port inserted and held therein;

10 Fig. 8 is a side perspective view of a device according to a second embodiment for mating with a stopcock or injection port and providing a shielded interface through which fluid can be injected;

Fig. 9 is a longitudinal cross-sectional view of the device of Fig. 8;

Fig. 10 is a transverse cross-sectional view of the device of Fig. 8;

15 Fig. 11 is a longitudinal cross-sectional view of the device of Fig. 8 including a movable cover which is shown in a closed position;

Fig. 12 is a longitudinal cross-sectional view of the device of Fig. 8 with the cover in an open position;

20 Fig. 13 is a side perspective view of a luer cap that is configured to cover the interface at which fluid is delivered to the IV system;

Fig. 14 is a side perspective view of a luer cap with a shield that is configured to cover the interface at which fluid is delivered to the IV system and the body of the device itself;

Fig. 15 is cross-sectional view showing a stopcock within integral protector; and

25 Fig. 16 is a cross-sectional view showing an injection port with integral protector.

Detailed Description of Certain Embodiments

Fig. 1 shows a general schematic of an exemplary intravenous (IV) medication delivery system 10. The system 10 includes a fluid source 20 (e.g., an IV fluid which is typically mostly formed of water) and typically, the fluid source 20 is in the form of an IV bag. A drip chamber 25 is located just below the IV bag 20. Inside, the drip chamber 25, one can see the fluid drip down from the IV bag 20 into IV tubing 30 (IV conduit in the form of flexible clear plastic tubing). Along the IV tubing 30 includes a roller clamp 35 which is a device that is used to control the rate at which the IV fluid infuses. If the roller clamp 35 is

rolled in one direction, the roller clamp 35 squeezes the IV tubing 30 more tightly, making it narrower and therefore making the fluid flow through the IV tubing 30 more slowly.

Conversely, if the roller clamp 35 is rolled in the opposite direction, the device 35 loosens its pinching of the IV tubing 30, making the IV tubing 30 less narrow, and allowing the IV fluid to flow through at a faster rate.

A slide clamp 40 is disposed along the IV tubing 30 and is configured to completely stop the IV from flowing without having to adjust the roller clamp 35. The slide clamp 40 operates by pinching the IV tubing 30 completely shut when the IV tubing 30 is slid into the narrowest part of the slide clamp 40.

A cannula 50 is a hollow needle, or more often a length of flexible plastic tubing which has been inserted into the vein (arm or hand) using a needle. The IV tubing 30 is typically taped to the patient's arm to prevent the cannula 50 from coming out when the patient moves. There are two different kinds of veins that can be used for the placement of the cannula; namely, a peripheral vein, which is any vein that is not in the torso, or a larger more central vein in the chest. Thus, a peripheral line is an IV that is attached to a peripheral vein (typically inserted to the arm of hand), while a central line is an IV that is attached to a vein in the chest.

As discussed herein, medicine or fluids other than those in the IV bag 20 are injected into the IV tubing 30 at one or more locations using one or more different techniques. For example, an inline injection port, generally shown at 60 in Fig. 1, is one type of device through which medication (or other fluid) can be delivered directly into the IV tubing 30 for rapid administration. Alternatively, and as shown also in Fig. 1, medication can also be delivered into the IV tubing 30 by use of a stopcock 70 that assists the caretaker in controlling fluid flow through IV delivery system 10. Each of the injection port 60 and stopcock 70 is described in more detail below. It will also be understood that the system 10 can be configured to deliver one more medications to the patient and thus, the system 10 can include one or more injection ports 60 and/or one or more stopcocks 70.

Moreover, the IV delivery system 10 can also include one or more other injection points at which fluid, such as medication, can be injected. For example, Fig. 1 shows a secondary line 90 that is in fluid communication with the IV tubing 30 (which represents the main IV line) and a proximal end of the secondary line 90 terminates in a secondary injection port 91 that is configured to mate with a fluid delivery member, such as a syringe, for injecting fluid into the secondary line 90 and then into the IV tubing 30 for delivery to the

patient. The main line (IV tube 30) and secondary line 90 can join one another at a catheter device 80 or the like that allows the combined fluid to flow to the patient.

In accordance with the present invention, each access point at which fluid (e.g., medication) is injected into the IV tubing 30 is protected against contamination (e.g., surface and/or airborne) by a device that can be thought of as a protector. As set forth below, depending on the type of access point (e.g., injection port or stopcock type injection port), the construction of the device (protector) will vary.

Figs. 1-7 illustrate a first device (first protector) 100 according to a first embodiment and configured to shield an injection port that is associated with intravenous medication delivery as a means for preventing contamination of the injection port. More specifically, the first device 100 is configured to mate and be used with one inline injection port 60. As shown in Figs. 1, 6 and 7, the injection port 60 can be in the form of a Y-shaped connector that is mounted at a desired location of the flow line (IV tubing 30) close enough to the lower or infusion end of the line to enable the fluid injection through the port 60 to be rapidly administered. The injection port 60 includes a main conduit section 62 that attaches to the IV tubing 30 and an upwardly raised arm 64 that extends radially outward from the main conduit section 62 a sufficient distance to provide ready access to a needle. The distal end of the arm 64 is capped with a needless injection port septum or a needle penetratable membrane 65 which can be formed of rubber or any other suitable material that is known and used in the art. Fluid, such as medication, is thus injected through the arm 64 into the main conduit section 62 where it joins the fluid from the IV bag and is delivered through the IV tubing 30 to the patient.

As mentioned herein, the illustrated device 100 is configured to be detachably coupled to the injection port 60. The device 100 is generally in the form of a structure that surrounds the injection port 60 and more specifically, surrounds the port septum 65 so as to prevent a foreign article, such as the caretaker's hand or fingers or any other material, from contacting the port septum 65. As discussed herein. The illustrated device 100 has a wall structure that extends above the port septum 65 so as to prevent easy access to the port septum 65 and has only limited access to the center of the device 100 in which the port septum 65 is located.

The device 100 can be in the form of a hollow structure that has a hollow interior 103 in which the port septum 65 is disposed with a wall of the device 100 surrounding and shielding the port septum 65 from contact with foreign matter. The device 100 also is configured to accommodate the injection port 60 in that the device 100 allows the main

conduit section 62 and the arm 64 to pass therethrough. The device 100 can thus be detachably coupled to the injection port 60.

In the illustrated embodiment, the device 100 has a generally spherical shaped body 101 with one end 102 being truncated and defining a main entrance into the hollow interior 103. It will be understood that the body 101 can have other shapes, such as a dodecahedron or other non-spherical shape so long as it has a hollow interior 103. Due to the spherical shape of the device 100, the truncation at the one end 102 defines a circular shaped opening (orifice) 105 that provides direct access to the hollow interior 103 and in particular, is sized so as to allow insertion of a syringe. An opposite end 104 of the body 101 also provides access to the hollow interior 103 in that a hole 110 is formed through the body 101. The hole 110 is formed at one end (a closed end) of a first slot 120 that is formed in the body 101. The first slot 120 extends from the hole 110 to the opening 105. As shown, the dimensions of the hole 110 can be enlarged relative to a width of the first slot 120. The hole 110 can be circular shaped and the first slot 120 can be a continuous slot having a uniform width. The first slot 120 receives the efferent limb of the IV tubing 30 and/or a portion of the inline injection port 60 that connects to the efferent limb.

The body 101 also includes a second slot 130 for receiving the afferent limb of the IV tubing 30 and/or a portion of the inline injection port 60 that connects to the afferent limb. The second slot 130 is formed in the body 101 at a location that is generally opposite the first slot 120; however, it will be appreciated that it can be formed at other locations as well to accommodate different types of injection ports 60. The second slot 130 is defined by a circular shaped hole 131 at a closed end of the second slot 130 and extends to the opening 105. Thus, each of the first and second slots 120, 130 can be accessed at the opening 105 and this permits, as described herein for insertion of the injection port 60 and the IV tubing 30. As shown, the sizes of the hole 110 and the hole 131 can be different or in some embodiments, the sizes can be the same. The first slot 120 has a longer length compared to the second slot 130.

Internally within the hollow interior 103 of the body 101 is a retaining structure that assists in holding the injection port 60 in place. For example, the retaining structure can be in the form of first and second supports (rails or brackets) 140, 150 that extend transversely across the body 101 and more particularly, extends transversely along a bottom surface of the body 101. Since the body 101 has a spherical shape, the bottom surface has a concave shape. The first and second supports 140, 150 can be in the form of upstanding rails that protrude upwardly from the bottom surface. The first and second supports 140, 150 are spaced apart

from one another and portions of the first and second supports 140, 150 are located on opposite sides of the first slot 120. This placement thus locates the first slot 120 centrally between the first and second supports 140, 150.

Since the hole 110 is preferably located at the center of spherical body 101, the center
5 portions of the first and second supports 140, 150 can be formed to accommodate the hole 110 which has an enlarged shape relative to the first slot 120 as mentioned herein. Thus, the inner surfaces of the first and second supports 140, 150 can have opposing arcuate shaped recessed portions 141, 151, respectively, so as to accommodate the injection port 60 that is received through the hole 110. The end portions of the first and second supports 140, 150
10 can be parallel to one another. Preferably, the heights of the first and second supports 140, 150 are the same. The first and second supports 140, 150 can be integrally formed with the body 101 as by a common molding process when the device 100 is formed of a moldable material. In Fig. 6, the first and second supports 140, 150 have been removed to allow for clearer illustration of the other components and the injection port 60.

It will be understood that the injection port 60 can comprise a rigid plastic piece that
15 is integral to the IV tubing which can have a more flexible material characteristic relative to the rigid plastic piece. It will therefore be understood that in one embodiment, the flexible IV tubing that is attached to the rigid plastic piece (injection port 60) can be the structures that pass through the slots 120, 130, while the rigid plastic piece can be contained within the body
20 101. Alternatively, a portion of the rigid plastic piece may pass through the slot 120. In any event, the slots 120, 130, permit routing of the IV tubing 30 in an inline injection port scheme. The body 101 is then disposed over the injection port 60 so as to surround the injection port 60.

The use of the device 100 with the injection port (an aseptic inline injection port) 60
25 will be understood with reference to Figs. 6 and 7. The injection port 60 is disposed within the hollow interior 103 by inserting the efferent limb of tubing (IV tubing 30) through the first slot 120 and by pulling the injection port 60 down through the opening 105. The injection port 60 is disposed between the first and second supports 140, 150 so that the injection port 60 becomes wedged therebetween. The afferent limb of the IV tubing 30 is
30 inserted through the second slot 130 to hold it in place during use. The injection port 60 is held in place by the first and second supports 140, 150, preventing twisting or dislodgement during use, and is shielded from contact with contaminated surfaces by the body (shell) 101. It will be understood that the construction of the body 101 is such that the side wall of the body 101 extends above the port septum 65 so as to prevent lateral contact with the port

septum 65. In the case of sphere shaped body 101, the side wall not only extends above the port septum 65 but it also has inward curvature and therefore, the side wall extends inwardly toward the port septum 65 so as to provide additional protective coverage of the port septum 65.

5 The body (shell) 101 thus at least partially encapsulates the port septum 65 of the injection port 60. Due to the spherical shape of the shell 101 and the location of the injection port 60 within the hollow interior 103 provides for the partial encapsulation of the injection port 60 and therefore, it is very difficult for a contaminated surface to come into contact with the port septum 65 since the only point of access to the port septum 65 is through the small
10 opening 105 that is located above the port septum 65.

 To use the injection port 60, the body (shell) 101 is grasped in the hand and a syringe is inserted through the opening 105 and medication is injected into the injection port 60 through the port septum 65. Grasping the body 101 positions the hand a distance from the injection port and thus, in the case that there is surface contamination on the hand, the
15 contamination is prevented from contacting the port septum 65.

 In yet another embodiment, the device 100 can be an integral part of the injection port 60 in that the device 100 is permanently coupled to the injection port 60 and is not meant to be separated therefrom. In other words, the shell is permanently connected to the injection port structure such that it forms a single part that is used with an IV line. In this embodiment
20 as in the others, the device 100 at least partially encapsulates the port interface of the injection port that receives the fluid. Any number of suitable manufacturing techniques can be used to form such a structure, including bonding and molding techniques.

 The device 100 can be formed of any number of different materials that are suitable for the intended application described herein. For example, the device 100 can be formed of
25 any number of different plastic materials that can have different degrees of flexibility (e.g., rigid, semi-rigid, etc.). The device 100 is of sufficient rigidity such that when the user grasps the body 101, the body 101 maintains its shape and does not collapse so as to cause the side wall of the body 101 to make contact with the port septum 65.

 Now turning to Figs. 1 and 8-10 which depict a second device (second protector) 200
30 in accordance with a second embodiment of the present and intended for use with the stopcock 70. There are many different types of stopcocks 70; however, all are configured such that a pivotable lever 71 controls flow of fluid through the stopcock 70 which is in fluid communication with the IV tubing 30. In the illustrated embodiment, the stopcock 70 has main legs 72, 72 to which the IV tubing 30 is inserted so as to place the stopcock 70 in the

fluid circuit. A side leg 75 is the portion of the stopcock 70 through which the medication is delivered. The pivotable lever 71 is manipulated so as to control delivery of fluid from the side leg 75 into the IV tubing 30. The side leg 75 is typically in the form of a luer connector to allow for easy connection to a syringe or the like. In the illustrated embodiment, the side
5 leg 75 comprises a female luer connector.

The second device 200 can be in the form of a hollow structure that has a hollow interior 203 into which a syringe or the like can be inserted for delivering the medication to the side leg (e.g., female luer connector) 75 of the stopcock 70 in a manner in which the attachment point between the fluid delivery member (e.g., a syringe) and the second device
10 200 is shielded. The device 200 is configured to be detachably coupled to the stopcock 70.

In the illustrated embodiment, the second device 200 has a generally spherical shaped body 201 with one end 202 being truncated and defining a main entrance into the hollow interior 203. It will be understood that the body 201 can have other shapes, such as a dodecahedron or other non-spherical shape so long as it has a hollow interior 203. Due to the
15 spherical shape of the device 200, the truncation at the one end 202 defines a circular shaped opening (orifice) 205 that provides direct access to the hollow interior 203 and in particular, is sized so as to allow insertion of a syringe. An opposite end 204 of the body 201 also provides access to the hollow interior 203 in that a hole or channel 210 is formed through which fluid exits the body 201.

The body 201 includes a connector 220 that is configured to mate with both the
20 stopcock 70 and the fluid delivery member (syringe). The connector 220 is located at the bottom of the body 201 and is securely coupled (attached) to the body 201 using any number of suitable techniques including a sealed snap-fit arrangement, use of a bonding agent, a molding process in which the connector 220 is integral to the body 201, etc. The connector
25 220 can be integrally formed with the body 201 and has a first end 222 that has a first connector part 230 and at an opposite second end 224, a second connector part 240 is formed. The first connector part 230 is disposed within the hollow interior 203 and is thus configured to mate with the fluid delivery member, while the second connector part 240 is disposed
30 outside of the body (shell) 201 and is thus configured to mate with the side leg 75 of the stopcock 70. For example, the first connector part 230 can be in the form of a female luer connector that is configured to mate with a distal end (e.g., a male luer connector) of the fluid delivery member. The second connector part 240 can be in the form of a male luer connector that is configured to mate with a female luer connector (side leg 75) of the stopcock 70,

thereby providing a fluid connection between the fluid delivery member (syringe) and the stopcock 70 to allow controlled delivery of medication or the like into the IV tubing 30.

It will also be appreciated that there are other types of luer connectors and the connector 220 can thus be substituted with any of these types of luer connectors.

5 Similar to the first device 100, the second device 200 is configured such that the fluid entry point, in this case, the first connector part 230 is shielded by the body 201 from contamination, such as surface contamination. It will be understood that the construction of the body 201 is such that the side wall of the body 201 extends above the first connector part 230 so as to prevent lateral contact with the first connector part 230. In the case of sphere
10 shaped body 201, the side wall not only extends above the first connector part 230 but it also has inward curvature and therefore, the side wall extends inwardly toward the first connector part 230 so as to provide additional protective coverage of the first connector part 230.

 To use the second device 200, the body 201 is grasped in the hand and a syringe is inserted through the opening 205 and is connected to the first connector part 230 (female luer
15 connector). The stopcock 70 is then opened, as by manipulating the lever, to permit inflow from the syringe and the medication is injected into the stopcock 70 (i.e., the side leg 75 thereof).

 In yet another embodiment, the second device 200 is configured to mate to a needless luer-lock injection port that includes a needless septum. This type of injection port includes a
20 luer type connector at one end which is configured to mate to the second connector part 240 of the device 200. Thus, device 200 is not limited to use of stopcock constructions but can be used with any luer type needleless injection port.

 In yet another embodiment shown in Fig. 15, the device 200 can be an integral part of the stopcock 70 in that the device 200 is permanently coupled to the side leg through which
25 medication is injected. In this embodiment, the stopcock and shell form a single part that is then used with the IV line. Any number of techniques can be used to form such structure including suitable bonding and molding operations. In this embodiment, as with the other embodiments, the shell still at least partially encapsulates the interface, such as a luer connector or septum, that receives fluid from the fluid delivery device (e.g., syringe).

30 Fig. 16 shows another embodiment in which a device 400 (which can have the same or similar construction as the device 200) is integral to the injection port 60 structure to form a single piece (part). The septum 65 is located within the hollow interior as in the embodiment of Fig. 7; however, since there are no slots, the IV tubing 30 passes and is routed outside the shell. The shell is thus coupled to the septum 65 and surrounds it.

Each of the first and second devices 100, 200 can be constructed so as to include a cap or cover structure that strategically covers either the main opening through which a syringe is inserted to access the needle penetrable membrane as in the case of device 100 and/or a cap or shield that covers the luer connector of the second device 200 and/or the main opening.

5 The device 100, 200 can be constructed such that it includes a cover or cap that can move between an open and closed position relative to the opening 105, 205. Figs. 11 and 12 show a cover 250 that is part of the device 200; however, it will be readily understood that the cover 250 can be constructed in the same manner with respect to the device 100 and in such case, closes off the opening 105. The cover 250 can be constructed such that it is in the
10 form of the truncated portion of the spherical shell (body) that was removed to form the opening 105, 205. The cover 250 thus completes the sphere and has a concave bottom surface and convex top surface as shown. It can be coupled to the remaining part of the device 100, 200 using any number of techniques, including the use of a hinge 255 as shown in the figures. To open the cover 250, a lip or tab 259 is formed at one edge of the cover 250.
15 The cover can be spring loaded as well to ensure that it remain in a closed position.

 In one embodiment, a cover or cap can be intended to cover at least the port septum 65 and in some embodiments, is intended to cover the opening 105. For example, a cap can be configured to fit over and be secured to the port septum 65 and since the cap is intended to be placed on the port septum 65 without having to touch the port septum 65, the cap can be
20 disposed at a distal end of an elongated handle. A user thus holds the cap by the handle and inserts the cap through the opening 105 and by manipulating the handle, the cap is placed on the port septum 65. A friction fit or luer connection can be formed between the cap and the membrane.

 As with the first device 100, the second device 200 can include a cap or cover to
25 shield the first connector part 230 from contaminants, such as airborne contaminants. As shown in Fig. 13, a luer cap 300 can be configured to mate with the first connector part 230 so as to cover and shield the first connector part 230. Since the user is not to insert a finger(s) through the opening 205, the luer cap 300 includes an elongated handle 305 that attaches as its distal end to the luer cap 300 and is of a length that permits the user to insert the luer cap
30 300 through the opening 205 and mate with the first connector part 230. For example, if the first connector part 230 has threads, the handle 305 can be rotated to cause rotation of the luer cap 300 to mate the luer cap 300 to the first connector part 230. It will be appreciated that the luer cap 300 can be a plastic cap and/or can contain an anti-microbial substance (e.g., Curoso™ available from 3M).

In yet another embodiment shown in Fig. 14, the proximal end of the handle 305 is connected to a cover 325 which is sized and shaped to fit and close the opening 205. For example, the cover 325 can have a disk (circular) shape. The cover 325 can have a handle 330 in the form of an upstanding protrusion that can be grasped by the user.

5 When the cover is designed to cover the opening 105, 205, a recessed landing can be formed about the opening for receiving the cover. The length of the handle is such that when the luer cap is coupled to the first connector part 230, the cover 325 covers the opening 205.

 It will also be understood that the second device 200 can be used with other types of needleless injection ports that have a luer connector. For example, the system 10 can include
10 a secondary branch defined by a segment of IV tubing. One end of the secondary branch terminates in a connector or the like (e.g., central catheter) in which the main IV line is also fluidly connected. The other end of the secondary branch terminates in a needless port which has an exposed luer connector that is configured to mate with the second device 200. For example, the exposed luer connector can be a female luer connector that mates with the male
15 luer connector 240 of the second device 200. In this way, the second device 200 is fluidly connected to the exposed luer connector of the secondary branch.

 In at least one embodiment of the present invention, the body of the device 100, 200 is formed so as to have an at least substantially spherically shape with the connector being contained in a bottom half of the body and the first opening is formed in a top 20% of the
20 body which is truncated so as to define the first opening. For example, the body can be at least 70% spherical in one embodiment, at least 75% in another, at least 80% in another and at least 90% in yet another embodiment. However, it is possible to truncate the sphere at other locations that are at or above the equator of the sphere depending in part upon the overall size of the sphere, etc.

25 The injection interface to which the fluid delivery member mates for delivery fluid to the IV line is preferably located in a bottom one half of the body of the device (protector) and can be located in a bottom one third of the body of the device (protector) and further can be located in a bottom one fourth of the body of the device (protector). In general, the lower the injection interface is located in the hollow interior of the body (shell), the more difficult it is
30 for contamination to occur since this injection interface is well shielded from surface contamination and the like. The above values are calculated based on the height of the body as measured from the open top edge of the shell to the bottom of the shell.

 Notably, the figures and examples above are not meant to limit the scope of the present invention to a single embodiment, as other embodiments are possible by way of

interchange of some or all of the described or illustrated elements. Moreover, where certain elements of the present invention can be partially or fully implemented using known components, only those portions of such known components that are necessary for an understanding of the present invention are described, and detailed descriptions of other portions of such known components are omitted so as not to obscure the invention. In the present specification, an embodiment showing a singular component should not necessarily be limited to other embodiments including a plurality of the same component, and vice-versa, unless explicitly stated otherwise herein. Moreover, applicants do not intend for any term in the specification or claims to be ascribed an uncommon or special meaning unless explicitly set forth as such. Further, the present invention encompasses present and future known equivalents to the known components referred to herein by way of illustration.

The foregoing description of the specific embodiments will so fully reveal the general nature of the invention that others can, by applying knowledge within the skill of the relevant art(s) (including the contents of the documents cited and incorporated by reference herein), readily modify and/or adapt for various applications such specific embodiments, without undue experimentation, without departing from the general concept of the present invention. Such adaptations and modifications are therefore intended to be within the meaning and range of equivalents of the disclosed embodiments, based on the teaching and guidance presented herein. It is to be understood that the phraseology or terminology herein is for the purpose of description and not of limitation, such that the terminology or phraseology of the present specification is to be interpreted by the skilled artisan in light of the teachings and guidance presented herein, in combination with the knowledge of one skilled in the relevant art(s).

While various embodiments of the present invention have been described above, it should be understood that they have been presented by way of example, and not limitation. It would be apparent to one skilled in the relevant art(s) that various changes in form and detail could be made therein without departing from the spirit and scope of the invention. Thus, the present invention should not be limited by any of the above-described exemplary embodiments, but should be defined only in accordance with the following claims and their equivalents.

What is claimed is:

1. A device for shielding an injection port that is located along tubing that is part of an intravenous (IV) medication delivery system, the device comprising:
a body having a hollow interior and a first opening for receiving a fluid delivery
5 member to allow passage of the fluid delivery member into the hollow interior while the body at least partially encapsulates the injection port, the body further including a first slot that opens into the first opening and terminates at a closed end and a second slot spaced from the first slot, the second slot opening into the first opening and terminating at a closed end, wherein the body includes first and second supports that are formed within the hollow interior
10 and extend transversely thereacross and are formed such that at least a portion of the first slot including the closed end is located therebetween, wherein the first and second supports are configured and positioned for receiving and holding the injection port therebetween, while the first and second slots are configured to allow passage of efferent and afferent limbs of the tubing while containing the injection port within the hollow interior.
- 15 2. The device of claim 1, wherein the body is formed of a molded plastic material.
3. The device of claim 1, wherein the body has a spherical shape with a top portion thereof being truncated so as to define the second opening.
4. The device of claim 3, wherein a side wall of the body is curved inwardly above the injection port and the first opening is positioned for placement directly above
20 the injection port.
5. The device of claim 1, wherein at least a portion of the first slot is located opposite the second slot.
6. The device of claim 1, wherein a length of the first slot is greater than a length of the second slot.
- 25 7. The device of claim 1, wherein the closed end of the first slot is located at a bottom end of the body.
8. The device of claim 1, wherein a height of the body is selected such that a septum of the injection port is contained within at least a bottom one half of the hollow interior.
- 30 9. A device for shielding a stopcock that is located along tubing that is part of an intravenous (IV) medication delivery system, the device comprising:
a body having a hollow interior and a first opening for receiving a fluid delivery member to allow passage of the fluid delivery member into the hollow interior, wherein the body includes a connector having a first connector part at a first end thereof and a second

connector part at a second end therefor, the first connector part being disposed within the hollow interior and a second connector part being disposed external to the body, the first connector part being at least partially encapsulated within the body thereby preventing inadvertent contact with the first connector part, wherein the first connector part is configured to mate with fluid delivery member and the second connector part is configured to mate with a connector associated with the stopcock for establishing a fluid connection between the fluid delivery member and the tubing through the stopcock.

10. The device of claim 9, wherein the body has a spherical shape with a top portion thereof being truncated so as to define the second opening.
11. The device of claim 9, wherein the body is formed of a molded plastic material.
12. The device of claim 9, wherein the first connector part comprises a female luer connector and the second connector part comprises a male connector.
13. The device of claim 10, wherein the connector is coaxial with a center longitudinal axis that passes through a bottom pole of the spherical shaped body.
14. The device of claim 9, wherein the body is at least substantially spherically shaped with the connector being contained at least in a bottom half of the body.
15. The device of claim 9, further including a cover that is coupled to the body and moves between an open position in which the first opening is accessible and a closed position in which the first opening is closed.
16. The device of claim 15, wherein the cover is pivotally coupled to the body by a hinge.
17. The device of claim 9, further including a cap disposed at a distal end of an elongated handle, the cap being configured to mate to the first connector part and the elongated handle having a length such that when the cap mates with the first connector part, a proximal end of the handle at least partially protrudes above the first opening so as to be accessible.
18. The device of claim 17, wherein the proximal end of the handle includes a shield that is configured to seal the first opening.
19. An intravenous (IV) medication delivery system comprising:
 - a source of fluid for delivery to a patient;
 - a main line that is in fluid communication with the source and terminates in a distal end that is configured for insertion into the patient;

an injection access port that is in fluid communication with the main line and has an interface that is configured to allow a fluid from a fluid delivery device to be injected into the main line; and

a protective shell that at least partially encapsulates the interface of the injection access port so as to prevent inadvertent contact with the interface, the protective shell including a first opening through which the medication delivery device can pass to reach the interface of the injection access port which is located within a hollow interior of the protective shell.

20. The system of claim 19, wherein the interface is located in at least a bottom half of the hollow interior of the protective shell.

21. The system of claim 19, wherein the protective shell has a truncated spherical shape with the first opening being formed along a top edge of the protective shell.

22. The system of claim 19, wherein the injection access port comprises one of an inline injection port and a stopcock.

23. The system of claim 19, wherein the fluid delivery device comprises a syringe.

24. The system of claim 19, wherein the injection access port comprises an injection port and the protective shell has a first opening for receiving a fluid delivery device to allow passage of the fluid delivery member into the hollow interior while the body at least partially encapsulates the injection port, the body further including a first slot that opens into the first opening and terminates at a closed end and a second slot spaced from the first slot, the second slot opening into the first opening and terminating at a closed end, wherein the body includes first and second supports that are formed within the hollow interior and extend transversely thereacross and are formed such that at least a portion of the first slot including the closed end is located therebetween, wherein the first and second supports are configured and positioned for receiving and holding the injection port therebetween, while the first and second slots are configured to allow passage of efferent and afferent limbs of the tubing while containing the injection port within the hollow interior.

25. The system of claim 24, wherein the protective shell has a spherical shape with a top portion thereof being truncated so as to define the second opening.

26. The system of claim 25, wherein a side wall of the protective shell is curved inwardly above the injection port and the first opening is positioned for placement directly above the injection port.

27. The system of claim 24, wherein a height of the protective shell is selected such that a septum of the injection port is contained within at least a bottom one half of the hollow interior.
28. The system of claim 19, wherein the injection access port comprises a stopcock and the protective shell has a first opening for receiving a fluid delivery member to allow passage of the fluid delivery member into the hollow interior, wherein the body includes a connector having a first connector part at a first end thereof and a second connector part at a second end therefor, the first connector part being disposed within the hollow interior and a second connector part being disposed external to the body, the first connector part being at least partially encapsulated within the body thereby preventing inadvertent contact with the first connector part, wherein the first connector part is configured to mate with fluid delivery member and the second connector part is configured to mate with a connector associated with the stopcock for establishing a fluid connection between the fluid delivery member and the tubing through the stopcock.
29. The system of claim 28, wherein the first connector part comprises a female luer connector and the second connector part comprises a male connector.
30. A method for shielding a fluid access port structure that is located along tubing that is part of an intravenous (IV) medication delivery system and is configured to permit injection of a fluid into the tubing, the method comprising:
at least partially encapsulating the fluid access port within a hollow interior of a protective shell such that the fluid access port is surrounded by the protective shell and a top edge of the protective shell lies above a top edge of the fluid access port.
31. The method of claim 30, wherein the fluid access port comprises an injection port and the protective shell has a first opening for receiving a fluid delivery device to allow passage of the fluid delivery member into the hollow interior while the body at least partially encapsulates the injection port, the body further including a first slot that opens into the first opening and terminates at a closed end and a second slot spaced from the first slot, the second slot opening into the first opening and terminating at a closed end, wherein the body includes first and second supports that are formed within the hollow interior and extend transversely thereacross and are formed such that at least a portion of the first slot including the closed end is located therebetween, wherein the first and second supports are configured and positioned for receiving and holding the injection port therebetween, while the

first and second slots are configured to allow passage of efferent and afferent limbs of the tubing while containing the injection port within the hollow interior.

32. The method of claim 30, wherein the injection access port comprises a stopcock and the protective shell has a first opening for receiving a fluid delivery member to allow passage of the fluid delivery member into the hollow interior, wherein the body includes a connector having a first connector part at a first end thereof and a second connector part at a second end therefor, the first connector part being disposed within the hollow interior and a second connector part being disposed external to the body, the first connector part being at least partially encapsulated within the body thereby preventing inadvertent contact with the first connector part, wherein the first connector part is configured to mate with fluid delivery member and the second connector part is configured to mate with a connector associated with the stopcock for establishing a fluid connection between the fluid delivery member and the tubing through the stopcock.

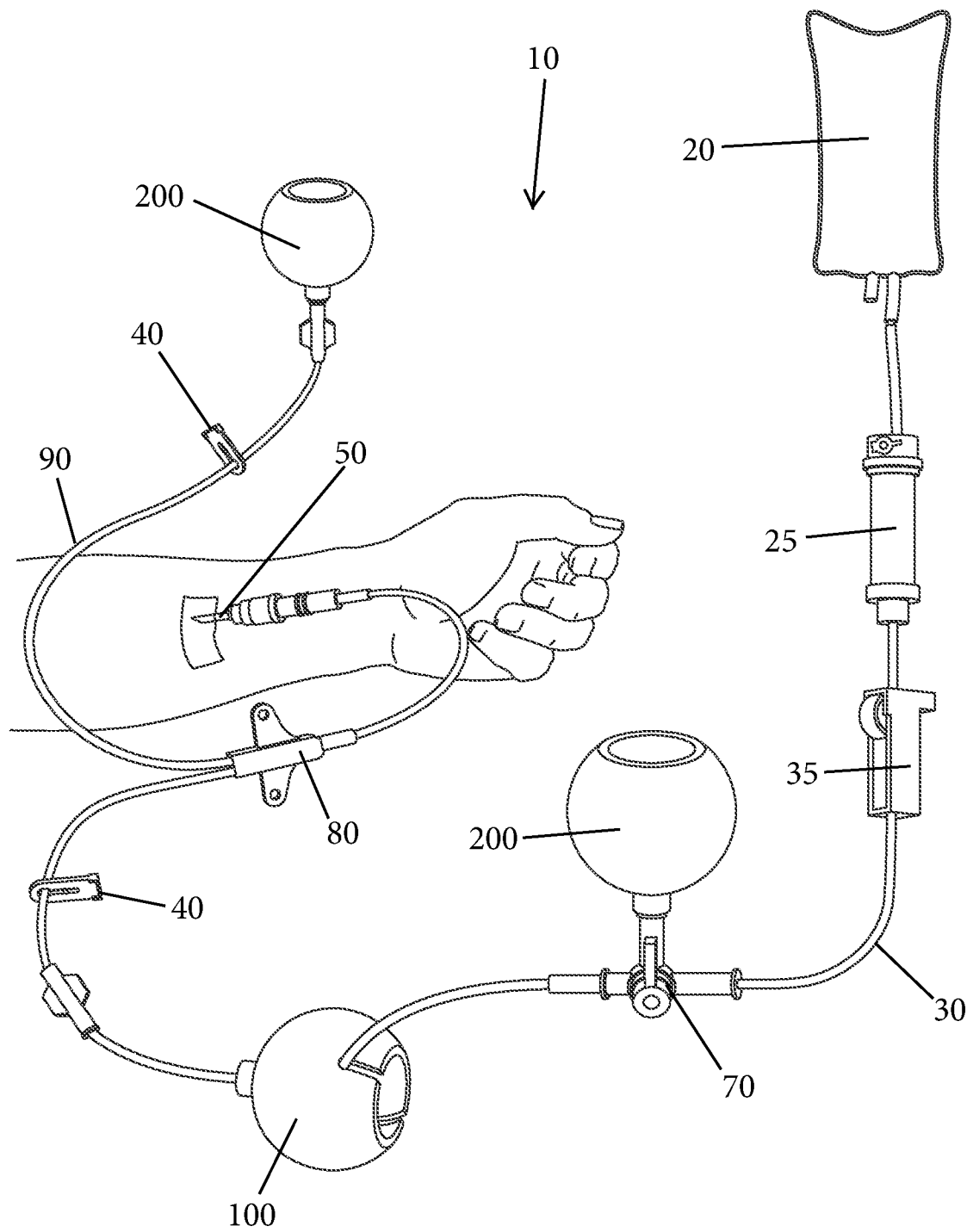


Fig. 1

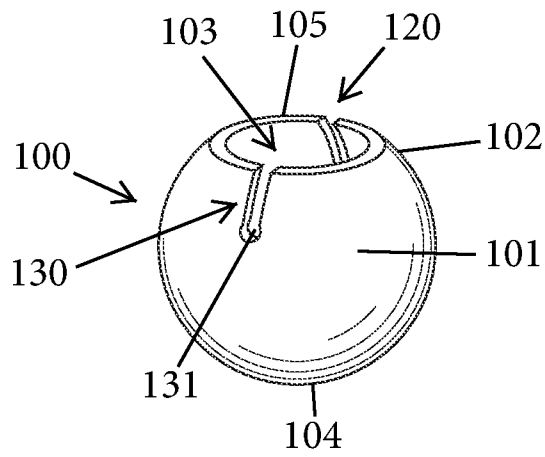


Fig. 2

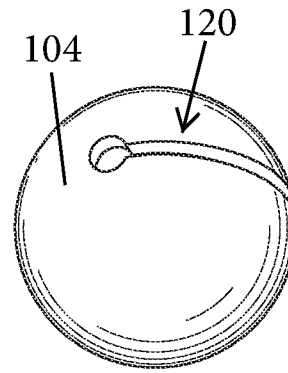


Fig. 3

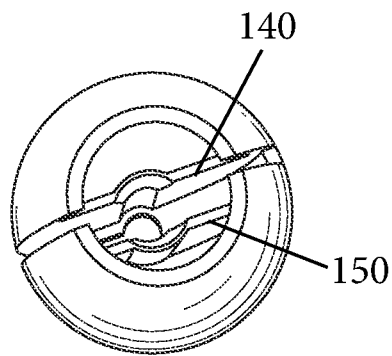


Fig. 4

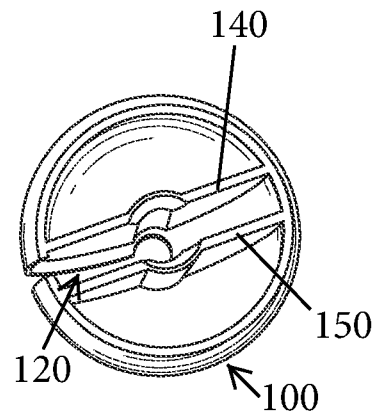


Fig. 5

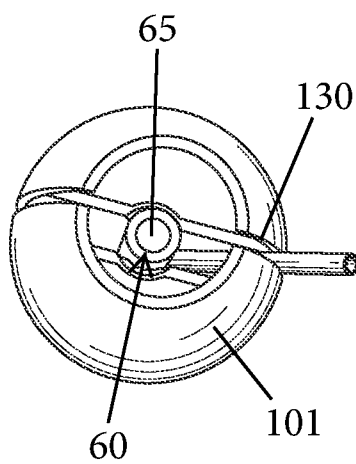


Fig. 6

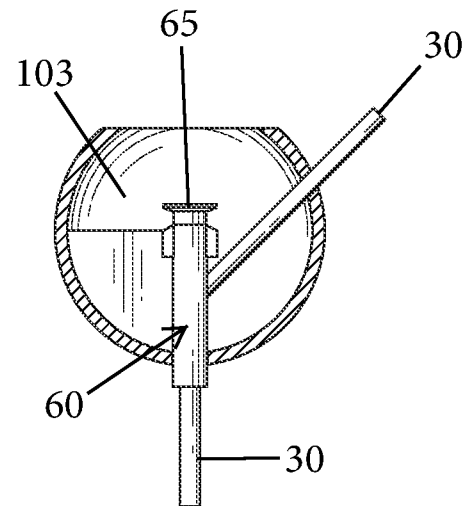


Fig. 7

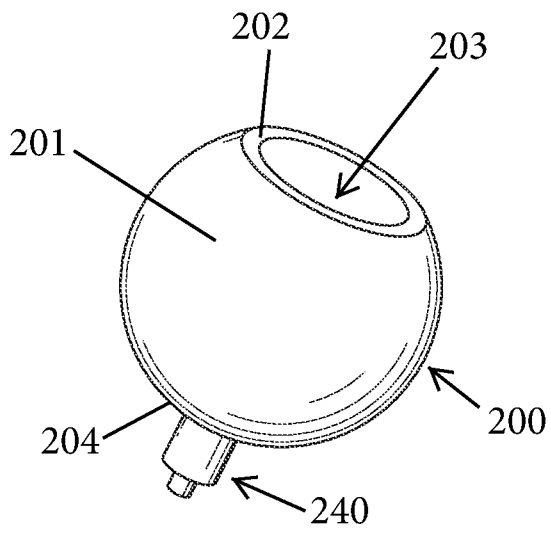


Fig. 8

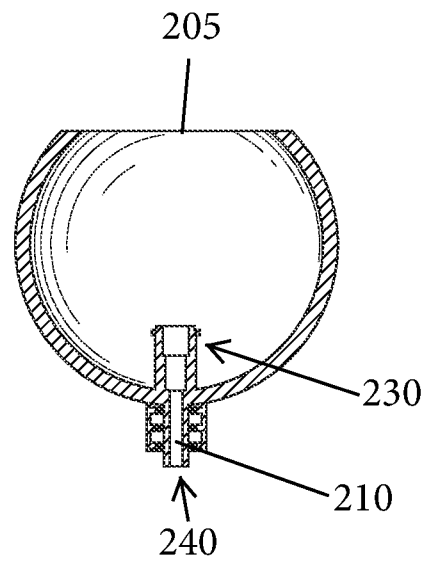


Fig. 9

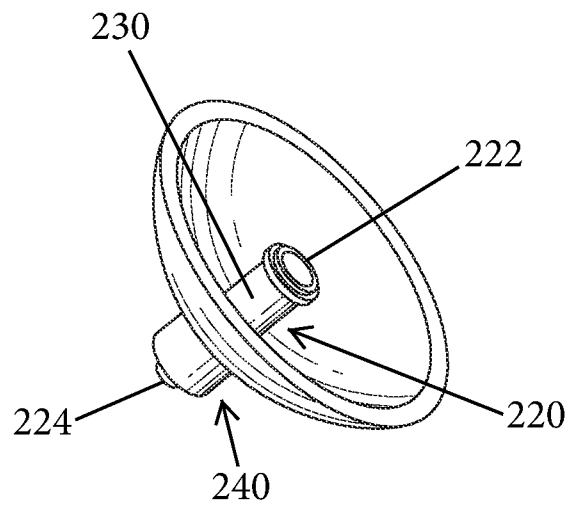


Fig. 10

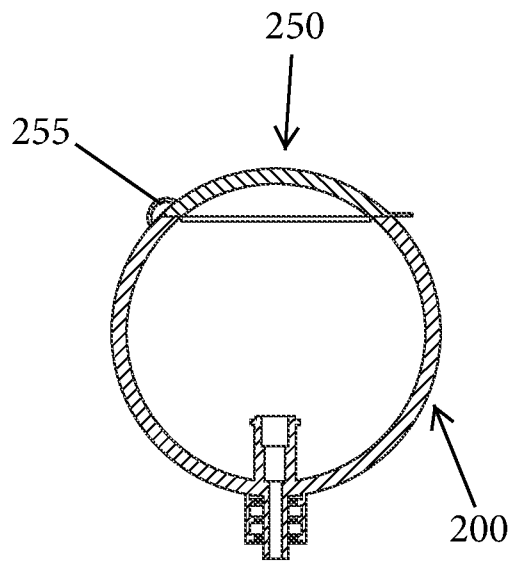


Fig. 11

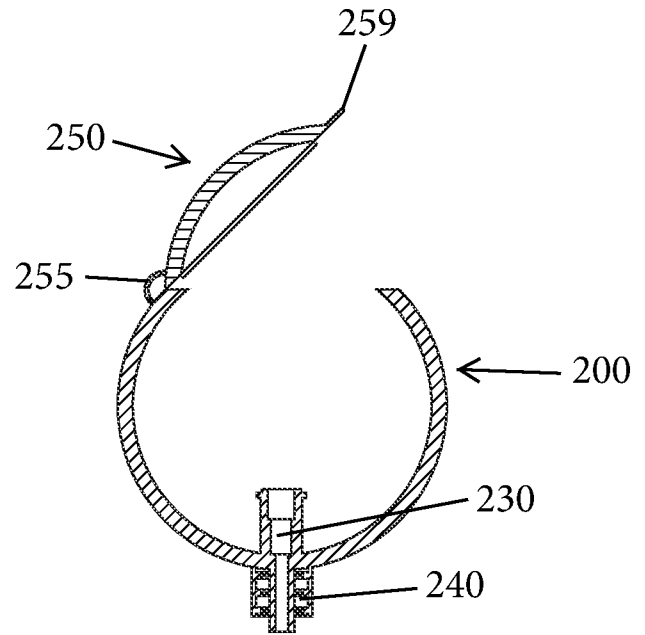


Fig. 12

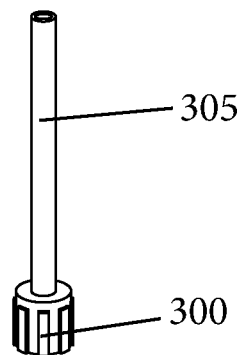


Fig. 13

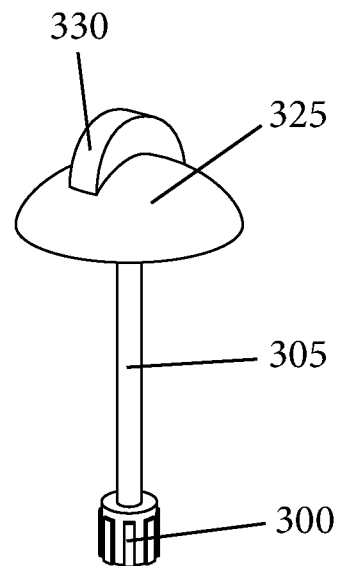


Fig. 14

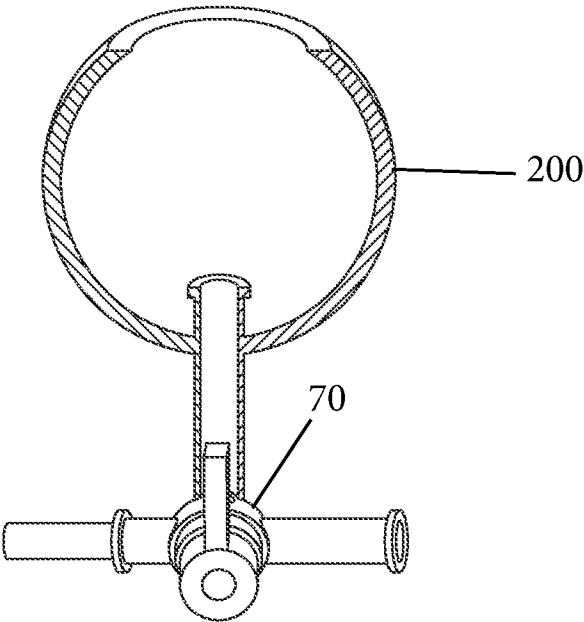


Fig. 15

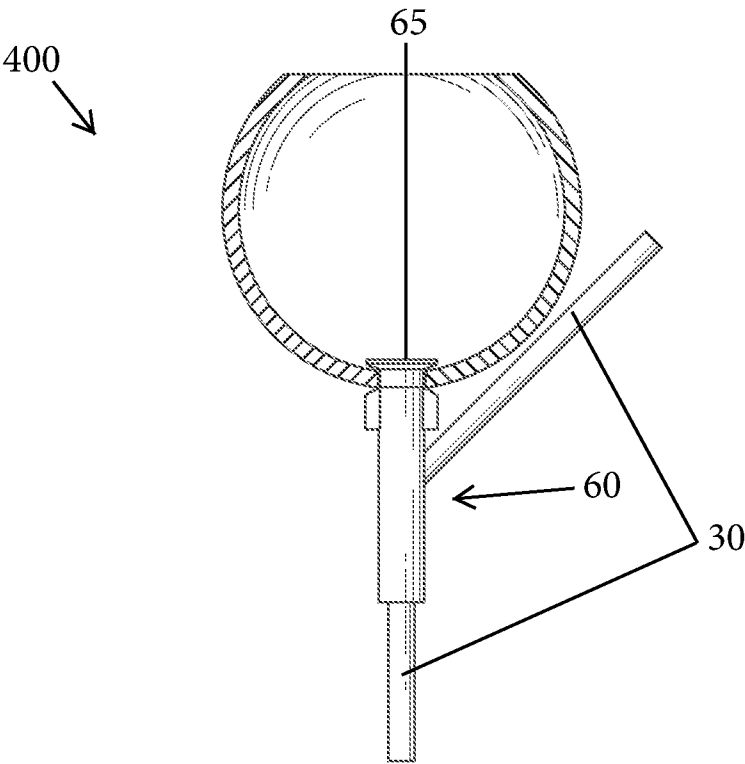


Fig. 16

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 17/24035

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

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

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

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

---- see extra sheet ----

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-8, 30-31

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 17/24035

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61M 39/10 (2017.01)

CPC - A61M 2039/042, A61M 39/165, A61M 2039/1066, A61M 39/04, A61M 39/10

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

See Search History Document

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

See Search History Document

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

See Search History Document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,964,785 A (DESECKI et al.) 12 October 1999 (12.10.1999) Entire document, especially Abstract, col 9, ln 66- col 10, ln 42 and FIGS. 2, 5-8.	30
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A		1-8, 31
A	US 2007/0083166 A1 (BOTICH et al.) 12 April 2007 (12.04.2007) Entire document, especially Abstract, para[0031]- para[0033], FIGS. 1, 6-9.	1-8, 31
A	US 2010/0307510 A1 (SABIN) 09 December 2010 (09.12.2010) Entire document, especially Abstract, para[0007]- para[0008], para[0011], para[0026]- para[0028] and FIGS. 1, 6.	1-8, 31
A	US 4,878,897 A (KATZIN) 07 November 1989 (07.11.1989) Entire document, especially Abstract and FIGS. 1-14.	1-8, 31
A	US 5,061,248 A (SACCO) 29 October 1991 (29.10.1991) Entire document, especially Abstract and FIG. 1.	1-8, 31
A	US 5,084,032 A (KORNBERG et al.) 28 January 1992 (28.01.1992) Entire document.	1-8, 30-31
A	US 4,946,445 A (LYNN) 07 August 1990 (07.08.1990) Entire document.	1-8, 30-31
A	US 3,583,460 A (FAUST et al.) 08 June 1971 (08.06.1971) Entire document.	1-8, 30-31
A	US 5,069,666 A (GERICKE) 03 December 1991 (03.12.1991) Entire document.	1-8, 30-31
A	US 5,423,775 A (CANNON) 13 June 1995 (13.06.1995) Entire document.	1-8, 30-31

☒ Further documents are listed in the continuation of Box C.☐ See patent family annex.

* Special categories of cited documents:

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

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search

31 July 2017

Date of mailing of the international search report

28 AUG 2017

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US, Commissioner for Patents

P.O. Box 1450, Alexandria, Virginia 22313-1450

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Authorized officer:

Lee W. Young

PCT Helpdesk: 571-272-4300

PCT OSP: 571-272-7774

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 17/24035

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 8,585,655 B2 (BIERMAN) 19 November 2013 (19.11.2013) Entire document.	1-8, 30-31
A	CN 204428594 U (AFFILIATED HOSPITAL QINGDAO UNIV) 01 July 2015 (01.07.2015) Entire document.	1-8, 30-31

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 17/24035

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

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I: Claims 1-8, 30-31; A device for shielding an injection port comprising the body further including a first slot that opens into the first opening and terminates at a closed end and a second slot spaced from the first slot, the second slot opening into the first opening and terminating at a closed end, wherein the body includes first and second supports that are formed within the hollow interior and extend transversely thereacross and are formed such that at least a portion of the first slot including the closed end is located therebetween, wherein the first and second supports are configured and positioned for receiving and holding the injection port therebetween, while the first and second slots are configured to allow passage of efferent and afferent limbs of the tubing while containing the injection port within the hollow interior; And methods of using said device.

Group II: Claims 9-18, 30, 32; A device for shielding a stopcock comprising a connector having a first connector part at a first end thereof and a second connector part at a second end thereof, the first connector part being disposed within the hollow interior and a second connector part being disposed external to the body, the first connector part being at least partially encapsulated within the body thereby preventing inadvertent contact with the first connector part, wherein the first connector part is configured to mate with fluid delivery member and the second connector part is configured to mate with a connector associated with the stopcock for establishing a fluid connection between the fluid delivery member and the tubing through the stopcock; And methods of using said device

Group III: Claims 19-30; An intravenous (IV) medication delivery system comprising: a source of fluid for delivery to a patient; a main line that is in fluid communication with the source and terminates in a distal end that is configured for insertion into the patient an injection access port that is in fluid communication with the main line and has an interface that is configured to allow a fluid from a fluid delivery device to be injected into the main line; And method of using said device.

*Claim 30 is common to all groups

The inventions listed as Groups I-III do not relate to a single inventive concept under PCT Rule 13.1 because under PCT Rule 13.2 they lack the same or corresponding technical features for the following reasons:

Special Technical Features
See Above

Common Technical Features

The groups I-III generally share the features: of a device and method of a protective device with a body having a hollow interior and a first opening for receiving a fluid delivery member to allow passage of the fluid delivery member into the hollow interior while the body at least partially encapsulates the member. However, these common technical features are anticipated by US 2007/0083166 A1 to Botich et al. (hereinafter: Botich). Botich describes a body (medical device cushion 10, FIG. 1; para[0025]) having a hollow interior (FIG. 1) and a first opening (top opening, FIG. 1) for receiving a fluid delivery member to allow passage of the fluid delivery member into the hollow interior while the body at least partially encapsulates the member (para[0007]-[0008],[0025]-[0027]; e.g. see access port 60, FIG. 6).

Accordingly, Groups I-III lack unity under PCT Rule 13.