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(54) **SYSTEMS AND METHODS FOR PHLEBOTOMY THROUGH A PERIPHERAL IV CATHETER**

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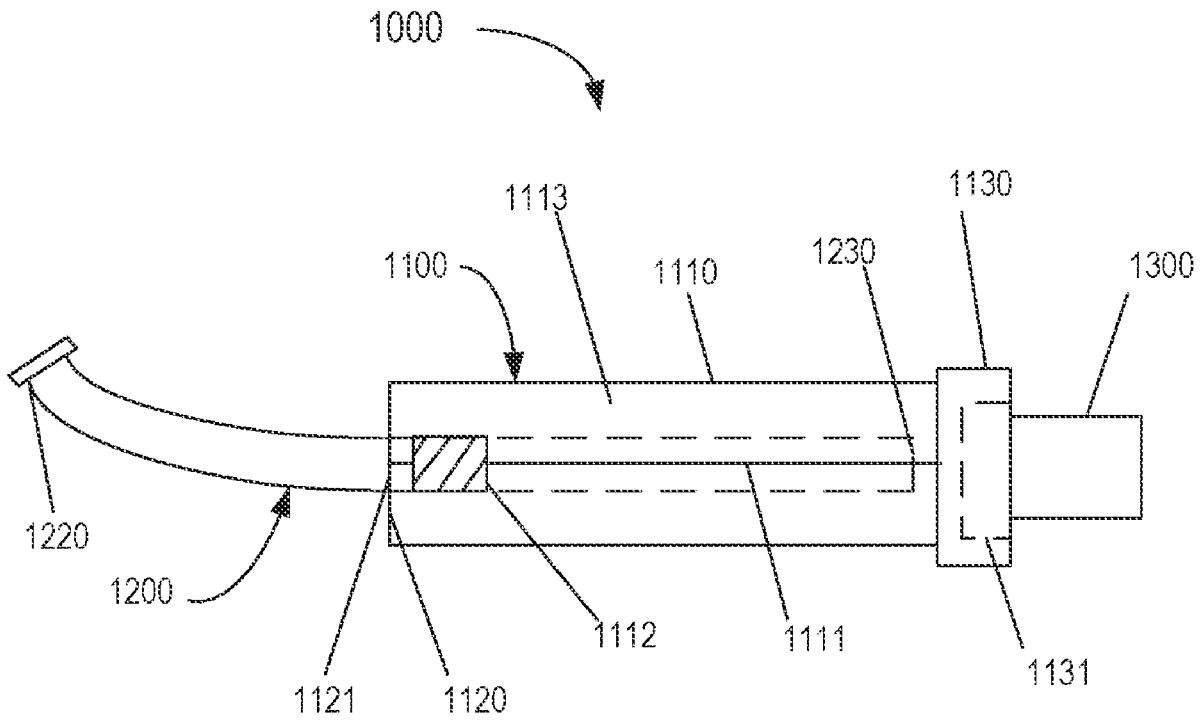
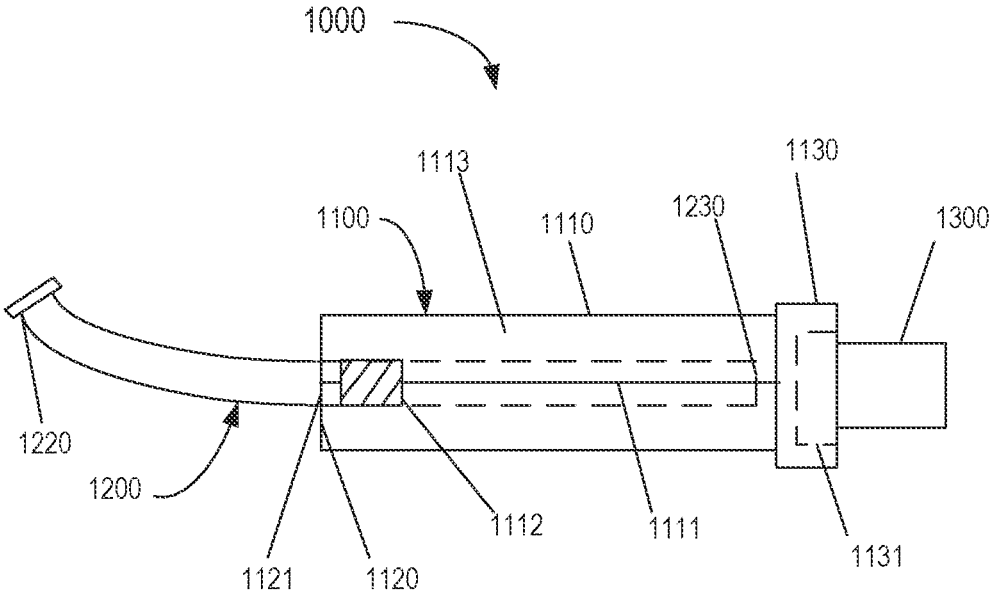
(57) **ABSTRACT**

An apparatus for performing phlebotomy through a peripheral intravenous line. The apparatus includes an introducer and a catheter configured to advance the catheter through a peripheral intravenous line. A y-adapter with a port of larger diameter is configured to receive the catheter and place in fluid communication with the peripheral intravenous line. When advanced the catheter is configured to transport a bodily fluid (i.e. blood) to a volume outside of the body.

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1113
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1100
1110
1230
1300
1220
1200
1112
1111
1131
1121
1120

FIG. 1

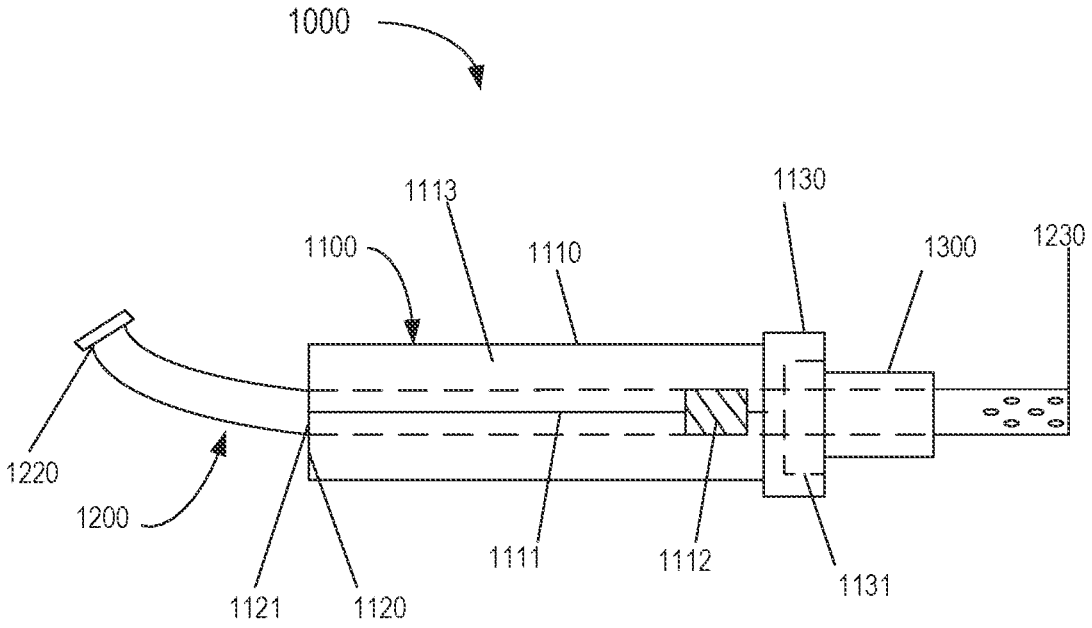
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FIG. 2

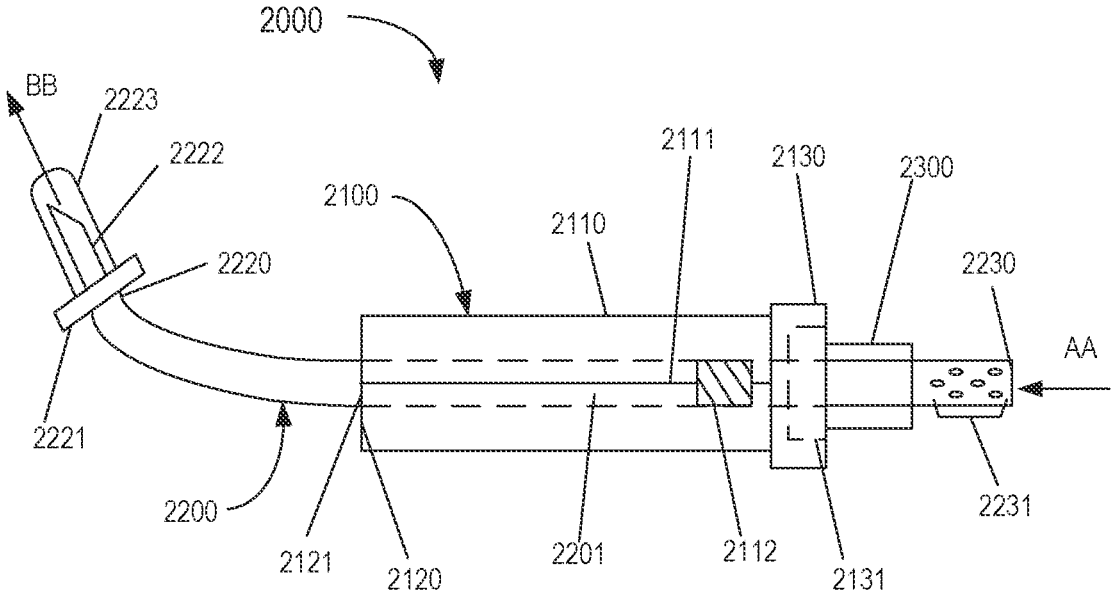
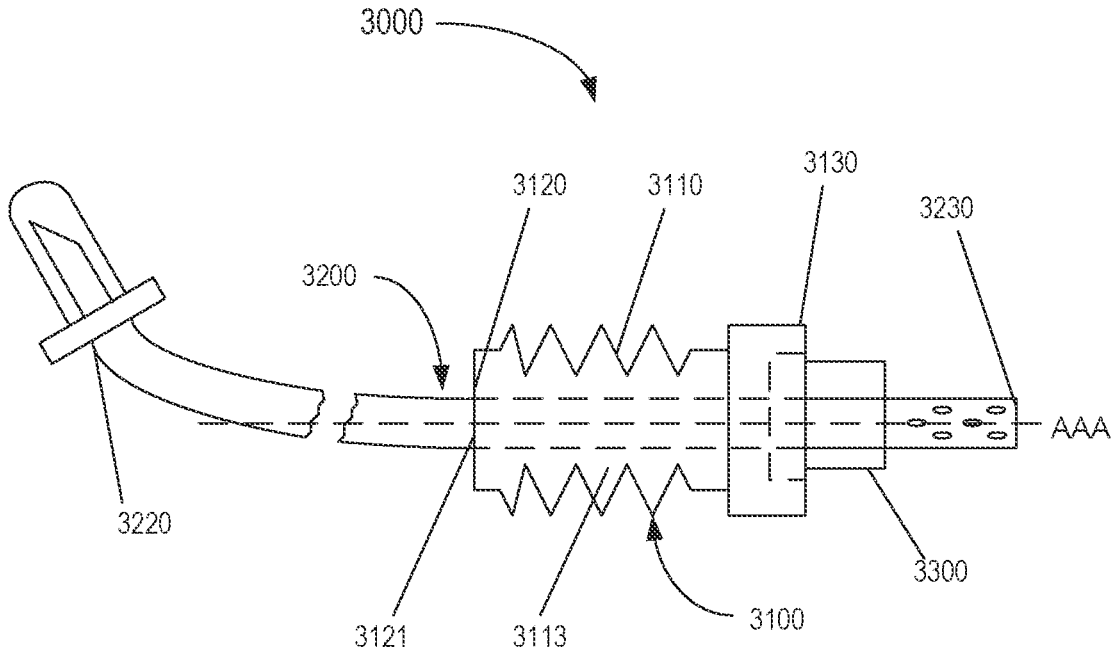

2000
BB
2223
2222
2220
2221
2200
2100
2110
2111
2130
2300
2230
AA
2231
2121
2120
2201
2112
2131

FIG. 3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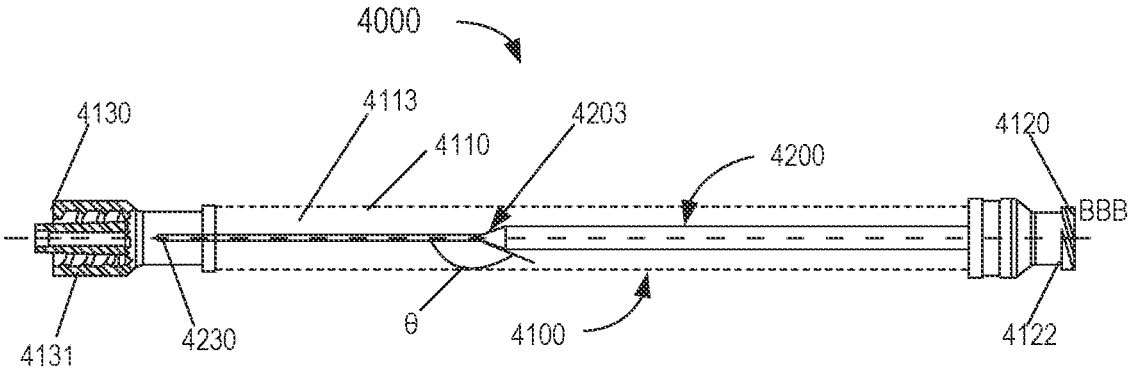
3120
3110
3130
3230
3200
AAA
3220
3300
3121
3113
3100

FIG. 4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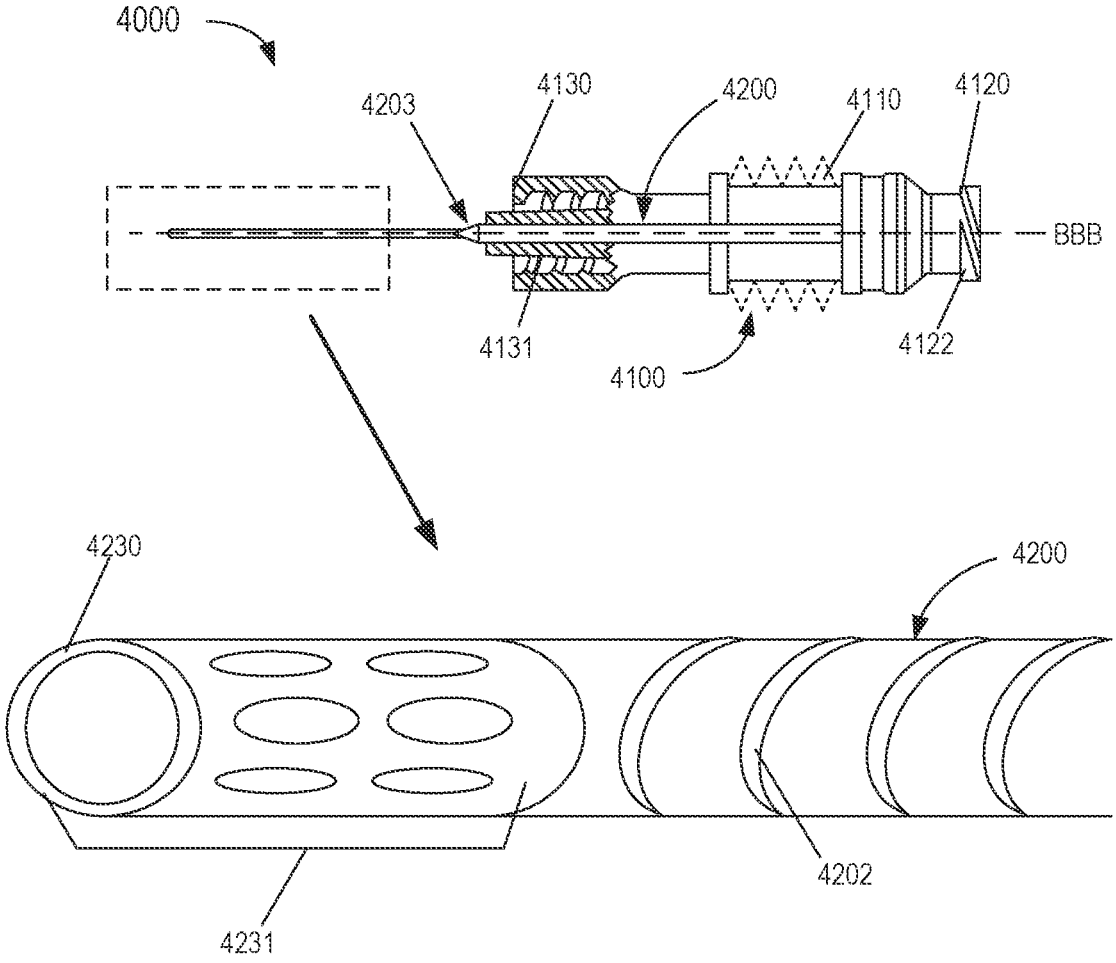
4130
4113
4110
4203
4200
4120
BBB
4131
4230
θ
4100
4122

FIG. 5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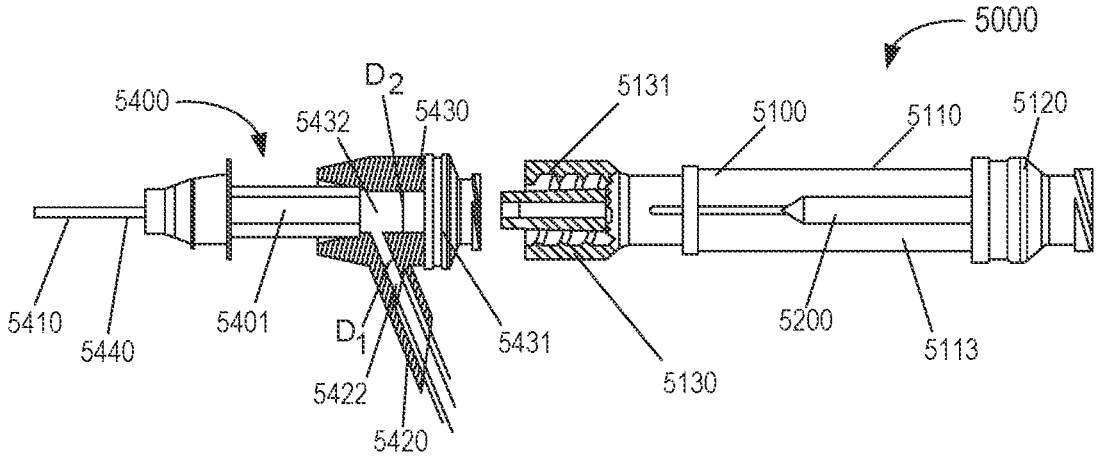
4202
4231

FIG. 6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5400
D2
5432
5430
5131
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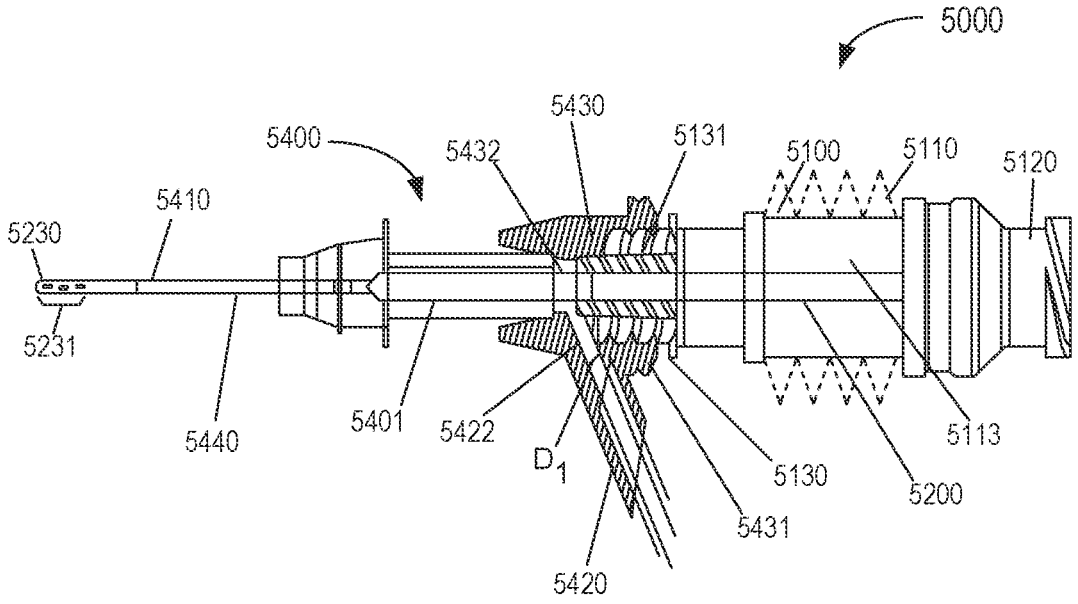
5401
D1
5431
5422
5420
5130
5200
5113

FIG. 7


5000
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5400
5432
5131
5100
5110
5120
5410
5230
5231
5440
5401
5422
D1
5130
5200
5113
5431
5420

FIG. 8

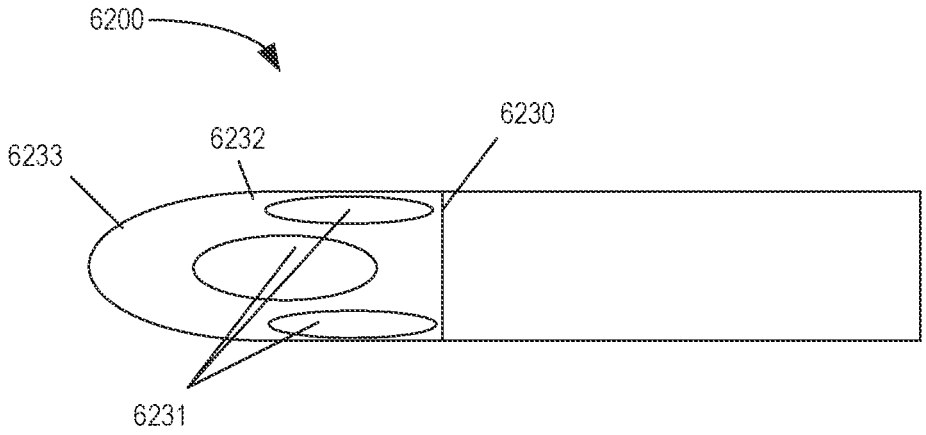

FIG. 9A

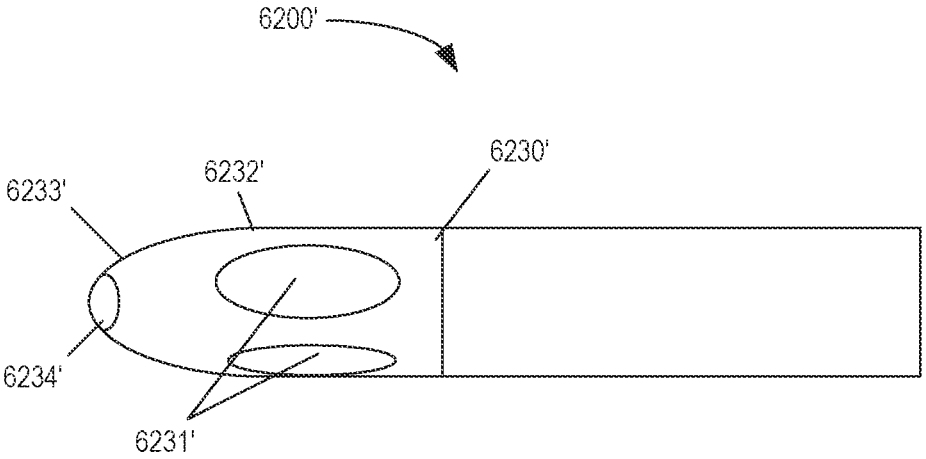

FIG. 9B

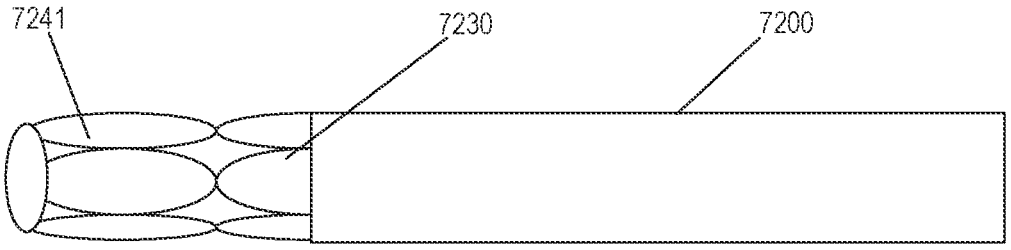

FIG. 10A

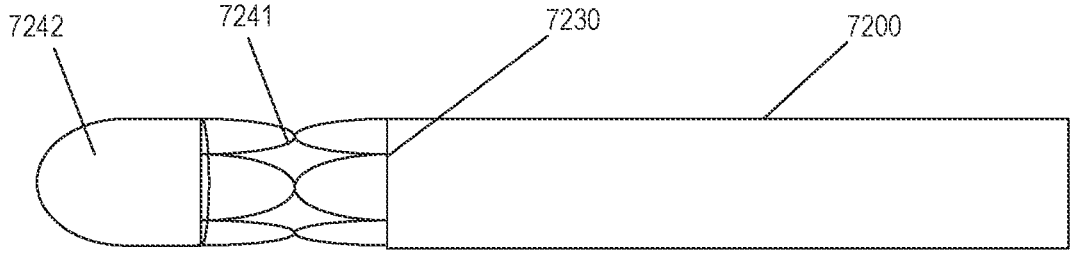

FIG. 10B

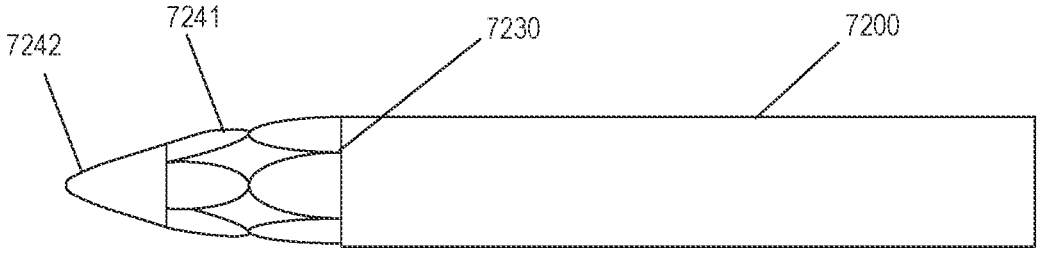

FIG. 10C

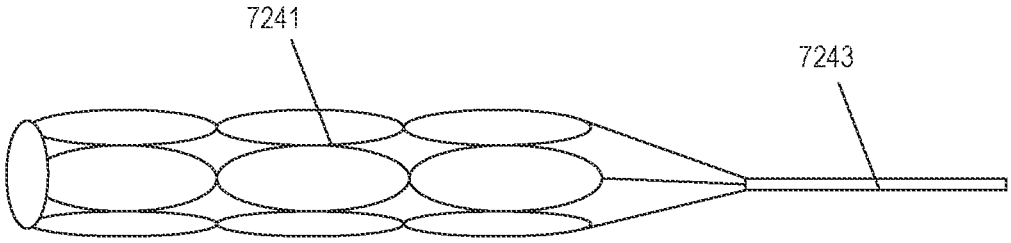

FIG. 11A

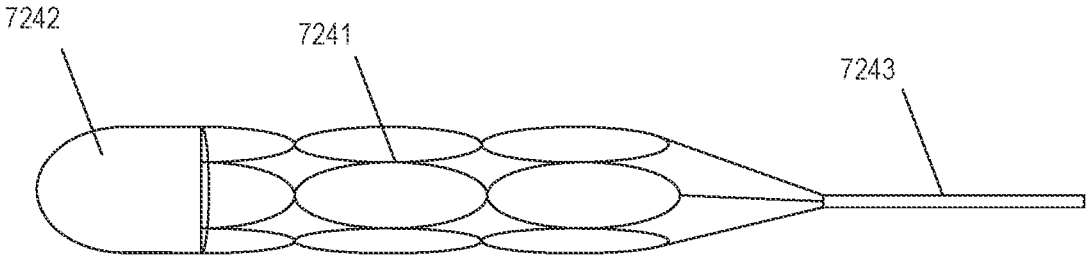

FIG. 11B

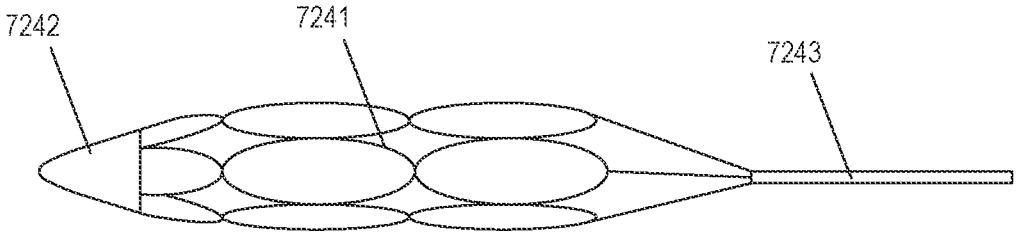

FIG. 11C

SYSTEMS AND METHODS FOR PHLEBOTOMY THROUGH A PERIPHERAL IV CATHETER

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation of U.S. patent application Ser. No. 16/120,582, entitled "Systems and Methods for Phlebotomy Through a Peripheral IV Catheter", filed Sep. 4, 2018, which is a continuation of U.S. patent application Ser. No. 14/933,403, entitled "Systems and Methods for Phlebotomy Through a Peripheral IV Catheter", filed Nov. 5, 2015 (now U.S. Pat. No. 10,064,576), which is a continuation of U.S. patent application Ser. No. 13/234,857, entitled "Systems and Methods for Phlebotomy Through a Peripheral IV Catheter", filed Sep. 16, 2011 (now U.S. Pat. No. 9,186,100), which claims priority to U.S. Provisional Patent Application Ser. No. 61/479,223 entitled "Systems and Methods for Phlebotomy Through a Peripheral IV Catheter", filed on Apr. 26, 2011, the disclosures of each of which are incorporated herein by reference in their entireties.

BACKGROUND

[0002] The embodiments described herein relate generally to medical devices. More particularly, the embodiments described herein relate to systems and methods for phlebotomy through an intravenous catheter.

[0003] The typical hospitalized patient encounters a needle every time a doctor orders a lab test. The standard procedure for blood extraction involves using a metal needle ("butterfly needle") to "stick" patients' veins in their arms or hands. Blood drawing is a manual, labor-intensive process, with the average patient requiring hours of direct skilled labor during a typical hospital stay. This needle stick is not only painful and a major source of patient dissatisfaction, but the nurses or specialized blood drawing personnel (phlebotomists) often have difficulty finding the vein in approximately 10-15% of patients, resulting in multiple, painful "stick" attempts. This results in significantly higher material and labor costs (needles and tubing must be disposed of after every attempt) and increased patient pain and bruising.

[0004] The current process for drawing blood is inefficient, taking on average 7-10 minutes, and more than 21 minutes for 10% of patients. These 10% of patients are referred to as Difficult Intra-Venous Access or more commonly as "tough stick" patients. If superficial veins are not readily apparent, blood can be forced into the vein by massaging the arm from wrist to elbow, tapping the site with the index and middle finger, applying a warm, damp washcloth to the site for 5 minutes, or by lowering the extremity over the bedside to allow the veins to fill. Each of these methods is time consuming and therefore costly.

[0005] Peripheral IV catheters (PIVs) are inserted into most patients while they are hospitalized and used for infusing fluids and medications. However, they are not designed for blood extractions. The failure rates for aspiration reach 20-50% when PIVs have been left inserted for more than a day. Blood extracted from PIVs is often hemolyzed, defined as the rupture of red blood cells and the release of their contents into surrounding fluid, resulting in a discarded sample and need to repeat the blood collection.

[0006] There are several mechanical barriers that can contribute to the shortcomings of extracting blood from a PIV. First, most catheters are formed from a soft bio-reactive polymer, the use of this material has led to a potential narrowing or collapse of the catheter as the negative pressure is applied for aspiration. Additionally, with longer indwelling times comes an increase in debris (e.g., fibrin/platelet clots) that build up on the tip of the catheter and within the lumen. This explains the relationship between failure rate and indwelling time. A third significant barrier is attributed to a "suction cup" effect, wherein the negative pressure created by aspiration through the catheter and the possible curved path of a vein result in the tip of the catheter adhering to the wall of the vein. As the negative pressure increases the vein can rupture resulting in "blowing the vein", a major concern for phlebotomists during aspiration through a PIV.

[0007] Thus, a need exists for an improved system and method for phlebotomy.

SUMMARY

[0008] Systems and methods for phlebotomy are described herein. In some embodiments, an apparatus includes an introducer, and a catheter. The catheter includes a proximal end and a distal end defining a lumen. The introducer includes a proximal end and a distal end defining a lumen and is configured to receive the catheter. An actuator, operatively coupled to the catheter, is configured to move the catheter between a first configuration, in which the catheter is substantially within the introducer, and a second configuration, in which the catheter is substantially outside the introducer. A locking mechanism, coupled to the distal end of the introducer, is configured to couple the introducer to a peripheral intravenous line. The catheter extends past an end of the peripheral intravenous line when in the second configuration.

BRIEF DESCRIPTION OF THE DRAWINGS

[0009] FIG. **1** is a schematic illustration of an apparatus according to an embodiment in a first configuration.

[0010] FIG. **2** is a schematic illustration of an apparatus according to an embodiment in a second configuration.

[0011] FIG. **3** is a detailed schematic illustration of an apparatus according to an embodiment in a second configuration.

[0012] FIG. **4** is a schematic illustration of an apparatus according to an embodiment in a second configuration.

[0013] FIG. **5** is a side view of an apparatus according to an embodiment in a first configuration.

[0014] FIG. **6** is a cross-sectional view of a portion of an apparatus according to an embodiment.

[0015] FIG. **7** is a side view of an apparatus according to an embodiment in a first configuration.

[0016] FIG. **8** is a side view of an apparatus according to an embodiment in a second configuration.

[0017] FIGS. **9**A and **9**B are side views of an apparatus according to embodiments.

[0018] FIGS. **10**A-**10**C are side views of an apparatus according to embodiments.

[0019] FIGS. **11**A-**11**C are side views of an apparatus according to embodiments.

DETAILED DESCRIPTION

[0020] Systems and methods for phlebotomy are described herein. In some embodiments, an apparatus includes an introducer, and a catheter. The catheter includes a proximal end and a distal end defining a lumen. The introducer includes a proximal end and a distal end defining a lumen and is configured to receive the catheter. An actuator, operatively coupled to the catheter, is configured to move the catheter between a first configuration, in which the catheter is substantially within the introducer, and a second configuration, in which the catheter is substantially outside the introducer. A locking mechanism, coupled to the distal end of the introducer, is configured to couple the introducer to a peripheral intravenous line. The catheter extends past an end of the peripheral intravenous line when in the second configuration.

[0021] In some embodiments, a method includes coupling an introducer sheath to a peripheral intravenous line (e.g., saline locked device, heparin locked device, or the like), the introducer sheath having a proximal end and a distal end. The method further includes advancing a catheter from a first position inside the introducer sheath and outside the peripheral intravenous line to a second position substantially outside the introducer sheath and inside the peripheral intravenous line. In some embodiments, the catheter has a length greater than a length of the peripheral intravenous line, while in other embodiments, the catheter, in the second position, is shorter than the peripheral intravenous line. A container is then coupled to the proximal end of the introducer sheath, the container being fluidically coupled to the catheter. The catheter is later withdrawn from the second position to the first position.

[0022] In some embodiments, a catheter has a proximal end and a distal end and defines a lumen therethrough. An introducer has a proximal end and a distal end and defines a lumen therethrough. The introducer is configured to receive the catheter therein. An adapter is coupled to the introducer. The adapter has a distal end configured to be coupled to a peripheral intravenous line. The adapter defines a first lumen and a second lumen. The first lumen has a first diameter and is configured to receive the catheter therethrough. The second lumen is orthogonal to the first lumen. An actuator is operatively coupled to the catheter and is configured to move the catheter between a first configuration and a second configuration. The catheter extends past the distal end of the adapter in the second configuration.

[0023] As used in this specification, the words "proximal" and "distal" refer to the direction closer to and away from, respectively, a user who would place the device into contact with a patient. Thus, for example, the end of a device first touching the body of the patient would be the distal end, while the opposite end of the device (e.g., the end of the device being manipulated by the user) would be the proximal end of the device.

[0024] As used herein, the term "stiffness" relates to an object's resistance to deflection, deformation, and/or displacement by an applied force. Stiffness can be characterized in terms of the amount of force applied to the object and the resulting distance through which a first portion of the object deflects, deforms, and/or displaces with respect to a second portion of the object. When characterizing the stiffness of an object, the deflected distance may be measured as the deflection of a portion of the object different from the portion of the object to which the force is directly applied. Said another way, in some objects, the point of deflection is distinct from the point where force is applied.

[0025] Stiffness is an extensive property of the object being described, and thus is dependent upon the material from which the object is formed as well as certain physical characteristics of the object (e.g., shape and boundary conditions). For example, the stiffness of an object can be increased or decreased by selectively including in the object a material having a desired modulus of elasticity, flexural modulus, and/or hardness. The modulus of elasticity is an intensive property of (i.e., is intrinsic to) the constituent material and describes an object's tendency to elastically (i.e., non-permanently) deform in response to an applied force. A material having a high modulus of elasticity will not deflect as much as a material having a low modulus of elasticity in the presence of an equally applied stress. Thus, the stiffness of the object can be increased, for example, by introducing into the object and/or constructing the object of a material having a high modulus of elasticity.

[0026] Similarly, a material's hardness is an intensive property of the constituent material and describes the measure of how resistant the material is to various kinds of permanent shape change when a force is applied. In discussing the hardness and the subsequent effect on the stiffness of a catheter, the Shore durometer scale is generally used. There are several scales for durometers with two commonly used in describing plastics, polymers, elastomers, and/or rubbers, namely, type A and type D, where type A is generally used for softer materials and type D is generally used for harder materials. The Shore durometer of a material is denoted by a number between 0 and 100, with higher numbers indicating a harder material, followed by the type of scale. For instance, a first material can be measured as having a Shore durometer of 40 Shore A and a second material can be measured as having a Shore durometer of 60 Shore D. Therefore, according to the Shore durometer scale, the second material is harder and thus, more stiff than the first material.

[0027] FIG. **1** is a schematic illustration of an apparatus **1000** for phlebotomy through a peripheral intravenous line or catheter in a first configuration according to an embodiment. The apparatus **1000** includes an introducer **1100** and a catheter **1200**. The catheter **1200** is movably coupled (e.g., slidably coupled, rotatably coupled, etc.) to the introducer **1100**. The introducer **1100** includes a sheath **1110** defining a lumen **1113** between a proximal end **1120** and a distal end **1130** and configured to house, at least partially, the catheter **1200**. The proximal end **1120** includes an opening or port **1121**, such that the catheter **1200** moves from the first, retracted configuration (FIG. **1**) to a second, extended configuration, (FIG. **2**). Similarly stated, the port **1121** at the proximal end **1120** of the introducer **1100** is configured such that the catheter **1200** may move through the port **1121** from the first configuration to the second configuration. Moreover, the port **1121** can be any suitable port such as an opening in the proximal end of the introducer **1100** and can include an o-ring, a gasket, or can be a self-sealing port and can be lubricated using any suitable lubrication to aid in the movement and/or sealing of the catheter **1200** therein. The distal end **1130** of the introducer **1100** includes a locking mechanism **1131** configured to fluidically couple a peripheral intravenous line **1300** to the introducer **1100** and place the catheter **2200** into fluid communication with the peripheral intravenous line **1300**. The locking mechanism **1131** can

be any suitable locking mechanism that creates a fluid-tight seal. In some embodiments, the locking mechanism can be a Luer lock or similar configuration. In some embodiments, the peripheral intravenous line **1300** is in a sealed configuration until the locking mechanism **1131** is coupled to the intravenous line **1300**. Once the locking mechanism **1131** is coupled to the intravenous line **1300**, the seal can be opened to allow access for the catheter **1200**.

[0028] FIG. **2** is a schematic illustration of an apparatus **1000** according to an embodiment in a second configuration. The apparatus **1000** includes an introducer **1100** and a catheter **1200**. The catheter **1200** defines a lumen **1201** between a proximal end **1220** and a distal end **1230** and may be any suitable diameter and stiffness. In particular, the catheter **1200** is between a 16-gauge and 26-gauge and having a Shore durometer of 20 Shore A to 50 Shore D. Said another way, the catheter **1200** can be any suitable diameter to be inserted through the peripheral intravenous line **1300** and can be sufficiently stiff to be advanced through the peripheral intravenous line **1300**. An actuator **1112** is operatively coupled to the catheter **1200** through a groove or slot **1111** in the introducer **1100**. The actuator **1112** is configured to move the distal end **1230** of the catheter **1200** from the first configuration, shown in FIG. **1**, to the second configuration substantially outside the introducer **1100**, as shown in FIG. **2**. In the second configuration, the length of the distal end **1230** of the catheter **1200** is greater than the length of the peripheral intravenous line **1300** and the catheter **1200** extends past the distal end of the intravenous line **1300**.

[0029] In some embodiments, the catheter **1200** can be moved to a third configuration in which it is retracted back into the introducer **1100**. The third configuration is substantially similar to the first configuration (FIG. **1**) in that the catheter **1200** is positioned in the introducer such that the user does not come into contact with bodily fluids. While in the first configuration and the third configuration, the apparatus **1000** can be disconnected from or connected to a peripheral intravenous line **1300**. Said another way, the apparatus **1000** can be in the first configuration before it is coupled to the peripheral intravenous line **1300**, then remain in the first configuration for a period of time after being coupled to the peripheral intravenous line **1300**. Similarly, the apparatus **1000** can be moved to the third configuration, can be disconnected from the peripheral intravenous line **1300**, and then remain in the third configuration.

[0030] FIG. **3** is a detailed schematic illustration of an apparatus **2000** according to an embodiment in a second configuration. The apparatus **2000** includes an introducer **2100** and a catheter **2200**. The catheter **2200** includes a distal end **2230** and a proximal end **2220**. The distal end **2230** of the catheter **2200** includes a set of openings **2231** such that when in the second configuration (i.e., when the distal end **2230** of the catheter **2200** is in the vein and outside the intravenous line) the openings **2231** act to transport a bodily fluid (i.e., blood) to a volume outside the catheter **2200**. The set of openings can be of any arrangement on the circumference of the catheter **2200** and can include the end of the catheter **2200**. Similarly stated, the catheter **2200** having the distal end **2230** can be substantially open at the tip surface. Each opening **2231** can be of any suitable shape or size and are not necessarily similar to any other opening included in the set of openings. In some embodiments, the catheter **2200** defines a single opening.

[0031] The proximal end **2220** of the catheter **2200** is fluidically coupled to a locking mechanism **2221**, as shown in FIG. **3**. The locking mechanism **2221** can be any suitable locking mechanism such as a Luer lock or the like. A needle **2222** is fluidically coupled to the locking mechanism and at least partially disposed within a sheath **2223**. The sheath **2223** can be any material with a suitable flexibility and/or compressibility such that the needle **2222** can extend through the sheath **2223** when engaged with a conventional phlebotomy fluid container (e.g., a Vacutainer®). The locking mechanism **2221** is configured to couple to a suitable fluid containment system such as a Vacutainer® holder (not shown in FIG. **3**) and place the needle **2222** in fluid communication with the fluid containment system. The sheath **2223** is configured to compress when the locking mechanism **2221** is coupled to the fluid containment system. This arrangement facilitates the passage of bodily fluids through the set of openings **2231** of the catheter **2200**, as shown in FIG. **3** by arrow AA, through the catheter **2200**, and exiting the catheter **2200** through the needle **2222**, as shown in FIG. **3** by arrow BB.

[0032] FIG. **4** is a schematic illustration of an apparatus **3000** for phlebotomy through a peripheral intravenous catheter in a second configuration according to an embodiment. The apparatus **3000** includes an introducer **3100** and a catheter **3200**. The introducer **3100** includes a sheath **3110** defining a lumen **3113** between a proximal end **3120** and a distal end **3130** and configured to house, at least partially, the catheter **3200**. The distal end **3130** of the introducer **3100** includes a locking mechanism **3131** configured to fluidically couple the introducer **3100** to a peripheral intravenous line **3300** and place the catheter **3200** into fluid communication with the peripheral intravenous line **3300**. The locking mechanism **3131** can be any suitable locking mechanism that creates a fluid-tight seal. In some embodiments, the locking mechanism can be a Luer lock or similar configuration. The sheath **3110**, having a given stiffness, is such that when applying a force to the proximal end **3120**, the sheath **3110** compresses along an axis AAA, advancing the catheter **3200** to the second configuration. Said another way, as the sheath **3110** of the introducer **3100** is compressed, the catheter **3200** moves from the first configuration (FIG. **1**) to a second configuration substantially outside the introducer **3100**, as shown in FIG. **4**. Furthermore, the stiffness of the sheath **3110** is an extensive property and as such can have a set of properties (i.e. material, thickness, shape and/or the like) to allow the sheath **3110** to compress along the axis AAA with the desired amount of force applied at the proximal end **3120** of the introducer **3100**. The set of properties allow the sheath **3110** to elastically deform (i.e. non-permanently) such that when the force is no longer applied to the proximal end **3120** of the introducer **3100**, the apparatus **3000** returns to the first configuration. In the second configuration, the distal end **3230** of the catheter **3200** extends past the distal end of the peripheral intravenous line **3300**. This arrangement allows for the transport of a bodily fluid to a volume outside the catheter **3200** and when complete, the apparatus **3000** returns to a third configuration, which is substantially the same as the first configuration.

[0033] FIG. **5** is a side view of an apparatus **4000** according to an embodiment in a first configuration. The apparatus **4000** includes an introducer **4100** and a catheter **4200**. The introducer **4100** includes a sheath **4110** defining a lumen

4113 between a proximal end **4120** and a distal end **4130** and configured to house, at least partially, the catheter **4200**. Although shown in FIG. **5** as being cylindrical, the introducer **4100** can be any suitable shape. Moreover, the lumen **4113**, defined by the interior walls of the sheath **4110** is not necessarily the same shape as the exterior walls of the sheath **4110**. Said a different way, the interior and exterior walls of the sheath **4110** can have a different cross sectional shape. The proximal end **4120** of the introducer **4100** is coupled to a locking mechanism **4122**. The locking mechanism **4122** can be any suitable locking mechanism such as a Luer lock or the like. The locking mechanism **4122** is configured to couple to a suitable fluid containment system such as a Vacutainer® holder (not shown in FIG. **5**) and place the catheter **4200** in fluid communication with the fluid containment system.

[0034] The distal end **4130** of the introducer **4100** includes a locking mechanism **4131** configured to fluidically couple a peripheral intravenous line (not shown in FIG. **5**) to the introducer **4100** and place the catheter **4200** into fluid communication with the peripheral intravenous line. The locking mechanism **4131** can be any suitable locking mechanism that creates a fluid-tight seal. In some embodiments, the locking mechanism **4131** is in a sealed configuration until the locking mechanism **4131** is coupled to the intravenous line. Once the locking mechanism **4131** is coupled to the intravenous line, the seal can be opened to allow access for the catheter **4200**. In addition, while in the unlocked configuration, the locking mechanism **4131** of the distal end **4130** and the locking mechanism **4122** of the proximal end **4120** create an isolated housing for the catheter **4200** therein. Stated similarly, prior to the proximal end locking mechanism **4122** and distal end locking mechanism **4131** being unlocked and before the catheter **4200** is in the second configuration, the catheter **4200** is sterile. Furthermore, the catheter **4200**, when in the second configuration and having contacted the desired bodily fluid, can be moved to the third configuration (i.e., returned to the first configuration) thereby isolating the used distal end **4230**.

[0035] The sheath **4110** has a given stiffness such that when a force is applied to the proximal end **4120** the sheath **4110** compresses along an axis BBB advancing the catheter **4200** to a second configuration (FIG. **6**). Said another way, as the sheath **4110** of the introducer **4100** is compressed, the catheter **4200** moves from the first configuration to the second configuration substantially outside the introducer **4100** (i.e., the sheath **4110** retracts). The properties of the sheath **4110** can be any set of properties discussed herein such that applying a desired amount of force to proximal end **4120** allows the sheath to compress along axis BBB. In the second configuration, the distal end **4230** of the catheter **4200** extends past the distal end of the peripheral intravenous line and allows for the transport of a bodily fluid to a volume outside of the catheter **4200**.

[0036] The catheter **4200** includes a distal end **4230** and tapered portion **4203**. The tapered portion is such that the diameter of the catheter **4200** is reduced at a given location, as shown in FIG. **5**. The taper angle θ can be any suitable angle such that the catheter **4200** is allowed to advance fully to the second configuration (FIG. **6**). Moreover, the taper angle θ is such that a laminar flow (i.e., smooth layered flow) is achieved. In some embodiments, the catheter **4200** can include a stiffening wire **4202**, as shown in the magnified portion of FIG. **6**, and can be configured to coil around the walls of the catheter **4200** providing the catheter **4200** with a desired stiffness. Moreover, the stiffening wire **4202**, being coiled around the catheter **4200**, can provide the flexibility to advance through a set of walls defining a lumen (i.e., veins, arteries, peripheral intravenous line, and/or the like) without kinking or binding. In addition, the stiffening wire **4202** can provide the catheter **4200** with enough stiffness to facilitate its advancement through the lumen.

[0037] The distal end **4230** of the catheter **4200** includes a set of openings **4231** such that when in the second configuration (i.e., when the distal end **4230** of the catheter **4200** is in the vein and outside the intravenous line) the openings **4231** act to transport a bodily fluid (i.e., blood) to a volume outside the catheter **4200**. The set of openings **4231** can be of any arrangement on the circumference of the catheter **4200** and can include the end of the catheter **4200**. Similarly stated, the catheter **4200** having the distal end **4230** can be substantially open at the tip surface. Although FIG. **6** shows the distal end **4230** of the catheter **4200** as substantially flat, the distal end **4230** may be any suitable shape, (e.g. conical or spherical) and can have any suitable degree of rounded edges. Each opening **4231** can be of any suitable shape or size and are not necessarily similar to any other opening **4231** included in the set of openings **4231**. The arrangement of the set of openings **4231** is configured to introduce a laminar flow through catheter **4200** to a volume substantially outside the catheter **4200** and thus avoid hemolysis.

[0038] In some embodiments, a blood collection system consists of two elements: (1) the introducer/catheter blood collection assembly described above; and (2) a y-adapter that is configured to attach to a standard 16 g or 22 g peripheral IV catheter. The y-adapter includes a dedicated port for the blood collection device and another standard port for conventional medicine and fluid infusion.

[0039] FIG. **7** is a cross-sectional view of y-adapter **5400** and an apparatus **5000** in a first configuration according to an embodiment. The apparatus includes an introducer **5100** and a catheter **5200**. The introducer **5100** includes a sheath **5110** defining a lumen **5113** between a proximal end **5120** and a distal end **5130** and configured to house, at least partially, the catheter **5200**. In some embodiments, the y-adapter **5400** is configured to be coupled between the introducer **5100** and intravenous line (not shown in FIG. **7**.). The y-adapter includes a distal end **5410** and defines two distinct ports. A first port **5420** of the y-adapter **5400** defines a first lumen **5422** with a first diameter D_1. The first port **5420** is configured such that the first port **5420** is substantially similar in size, shape, configuration, and functionality of a conventional y-adapter. Moreover, the first port **5420** is configured such that the backflow of a bodily fluid cannot exit the first port **5420**. More specifically, the first lumen **5422** defined by the walls of the first port **5420** can be such that the lumen **5422** restricts the backflow of a bodily fluid (i.e. blood). In some embodiments, the backflow can be prevented using a valve, screw cap, flip cap, port, and/or the like. A second port **5430** of the y-adapter **5400** defines a second lumen **5432** with a second diameter D_2. The second diameter D_2 can be larger than the first diameter D_1, as shown in FIG. **7**, in some embodiments, the second diameter D_2 can be similar or smaller than the first diameter D_1. More particularly, the diameter D_2 of the second port **5430** is large enough to accept up to, for example, an 18-gauge catheter.

The y-adapter can be of any suitable material and/or be of similar material to that of a conventional y-adapter.

[0040] The first lumen **5422** defined by the first port **5420** and the second lumen **5432** defined by the second port **5430** converge to a common lumen **5401** before the distal end **5410** of the y-adapter **5400**, as shown in FIG. **7**. The second port **5420** is configured such that the second lumen **5432** is substantially coaxial with the common lumen **5401** and has a diameter substantially the same as the diameter D_2. In some embodiments, the walls that define the common lumen **5401** and the walls that define the second lumen **5432** are similar. The second port **5430** is fluidically coupled to a locking mechanism **5431** configured to couple the y-adapter to the introducer **5100**. The locking mechanism **5431** can be a Luer lock or the like. In some embodiments, the y-adapter **5400** is in a sealed configuration until coupled to the locking mechanism **5131** at the distal end **5130** of the introducer **5100**. Once the locking mechanism **5431** is coupled to the introducer **5100**, the seal can be opened to allow access for the catheter **5200** to advance to a second configuration, shown in FIG. **8** (note the introducer is not shown coupled to the y-adapter in FIG. **8**).

[0041] In some embodiments, the distal end **5410** of the y-adapter **5400** is coupled to a peripheral intravenous line **5440** such as, for example, a conventional peripheral intravenous line. In some embodiments, the y-adapter **5400** is monolithically formed with the peripheral intravenous line **5440**. In some embodiments, the distal end **5410** of the y-adapter **5400** can be coupled to a peripheral intravenous line using any suitable locking mechanism. Similarly, the second port **5420** of the locking mechanism **5431** configured to couple the y-adapter **5400** to the introducer **5100** can monolithically formed with the introducer **5100**. Said another way, in some embodiments, a separate introducer is not required, but rather a portion of the y-adapter can serve as the introducer.

[0042] As shown in FIG. **8**, the distal end **5230** of the catheter **5200** in the second configuration is advanced substantially past the peripheral intravenous line **5440**. The distal end **5230** of the catheter **5200** includes a set of openings **5231** such that when in the second configuration (i.e., when the distal end **5230** of the catheter **5200** is in the vein and outside the intravenous line) the openings **5231** act to transport a bodily fluid (i.e., blood) to a volume outside the catheter **5200**. The set of openings can be of any arrangement on the circumference of the catheter **5200** and can include the end of the catheter **5200**. Similarly stated, the catheter **5200** having the distal end **5230** can be substantially open at the tip surface. Each opening **5231** can be of any suitable shape or size and are not necessarily similar to any other opening included in the set of openings. The catheter **5200**, in the second configuration and having transported the desired bodily fluid, can be returned to the third configuration (i.e., the first configuration) (FIG. **7**) thereby isolating the used distal end **5230**.

[0043] While catheters are described herein as including a distal end of a particular configuration (i.e., with circumferential openings, etc.), in some embodiments the distal end of the catheter can include a different structure configured to facilitate the drawing of blood through the catheter. For example, FIG. **9**A illustrates a catheter **6200** that includes a distal end **6230** with a bullet-shaped tip **6232**. The bullet-shaped tip **6232** includes an end portion **6233** configured to be a substantially closed rounded tip and, as such, can be used to move through clots existing within a peripheral intravenous line. The bullet-shaped tip **6232** includes a set of side-wall openings **6231** that are operative to transport a bodily fluid (i.e., blood) to a volume outside the catheter **6200**. In some embodiments, such as, for example, a catheter **6200'** shown in FIG. **9**B, a bullet-shaped tip **6232'** includes an end portion **6233'** that defines an end opening **6234'**. In such embodiments, the bullet-shaped tip **6232'** includes a set of side-wall openings **6231'**. The end opening **6234'** and the side openings **6231'** can be configured to produce a laminar flow and act to transport a bodily fluid (i.e., blood) to a volume outside the catheter **6200'**. While the openings **6231**, **6231'** are illustrated as having a particular configuration, the shape and orientation/relative position of the openings can be varied to facilitate the fluid flow through the catheter.

[0044] In some embodiments, for example those shown in FIGS. **10**A-**10**C, a catheter **7200** includes a distal end **7230** with a wireframe tip **7241** having a stent-like configuration. The wireframe tip **7241** can be a flexible mesh configured to extend away from the distal end **7230** of the catheter **7200**. The wireframe tip **7241** can act to transport a bodily flow (i.e., blood) to a volume outside the catheter **7200**. In some embodiments, the wireframe tip **7241** can include a capped end **7242**. The capped end **7242** can be any suitable size, shape, or configuration and, in some embodiments, can include any suitable number of openings.

[0045] In some embodiments, the wireframe tip **7241** can be connected to a guide wire **7243** and used without an additional catheter, as shown in FIGS. **11**A-**11**C. Similarly stated, the wireframe tip **7241** can be inserted into an existing peripheral intravenous line via a guide wire and without the catheter of FIG. **10**. In this manner, the wireframe tip **7241** can act as a stent and support the walls of the vein such that blood can be drawn through the existing peripheral intravenous line. In such a configuration, the wireframe tip **7241** can be positioned within the existing peripheral intravenous line at any suitable location. For example, the wireframe tip can be positioned adjacent the distal end of the intravenous line.

[0046] The components of the blood draw apparatus and the y-adapter can be packaged together or separately. The y-adapter can also be sold in a package with other IV dressing materials. In some embodiments, the y-adapter can remain on the IV as long as the IV is in the patient.

[0047] The blood draw apparatus can be used with a variety of peripheral IVs. The apparatus allows efficient blood draw while still maintaining the integrity of the sample. In some embodiments, for example, the apparatus will facilitate 20 ml of blood to be drawn in approximately 1-2 minutes. While extracting blood, the blood flow can be laminar to avoid turbulence in the catheter to minimize hemolysis.

[0048] While the blood draw apparatus can be used m a variety of settings (ER, inpatient, etc.), two examples of scenarios are described herein. In the first scenario, the patient has a single peripheral IV. In the second scenario, which is typically less common, the patient has a dedicated second peripheral IV just for phlebotomy purposes. Only one y-adapter is required per patient, and can be attached for the life of the IV, for example, which is typically 3-4 days. A new catheter can be used for each blood draw.

[0049] The assembly of the blood draw apparatus can be the same in either scenario. First, the apparatus is coupled to the y-adapter. Second, the catheter is advanced through the

y-adapter and pushed through the peripheral IV catheter into the patient's vein. Once in the vein, a syringe or a negative pressure collection container/tube (e.g., a Vacutainer® tube) is connected to the rear port and fluidically coupled to the catheter to draw and store blood.

[0050] The following scenario is provided by way of example. The nurse or phlebotomist inserts a peripheral IV into a patient's arm. The peripheral IV is inserted following standard guidelines and the y-adapter is attached. When it is time to draw blood, the provider can turn off the IV, if it is on, for approximately 1-5 minutes to allow medicine or IV fluids to disperse from the blood-drawing site. To draw the blood sample, the provider attaches the blood draw apparatus to the blood draw port on the y-adapter, advances the internal catheter through the peripheral IV and into the vein. Next, the provider can attach the negative pressure collection container(s)/tube(s) to the apparatus (i.e., place the tube in fluid communication with the blood draw apparatus) to extract the blood sample. In use, a user can discard, for example, the first 3-6 ml of the fluid or blood sample as "waste" then using the next tube(s) as the intended sample. This "wasting" procedure ensures all of the dead space fluid, like saline or medications, are cleared from the vein, peripheral IV and y-adapter as to not contaminate the testing sample being drawn.

[0051] In the scenario in which there is a dedicated peripheral IV line for blood draw purposes, the provider inserts a peripheral IV into one arm to administer medicine and another peripheral IV into the opposite arm specifically for blood drawing purposes. When it is time to draw blood, the provider simply follows the steps mentioned above and there is no need to wait the 2-3 minutes to allow fluid or medicine dispersal as in the first scenario.

[0052] Each of the components discussed herein can be monolithically constructed or can be a combination of parts. For example, in reference to FIG. **7**, the y-adapter **5400** and the introducer **5100** are coupled using locking mechanisms **5431** and **5131**, respectively. The y-adapter **5400** and the introducer **5100** can be the same component, wherein the y-adapter is an integral part of the introducer **5100** and vice-versa. Other aspects of the apparatus shown and described can be modified to affect the performance of the apparatus. For example, the openings in the set of openings described herein at the distal end of the catheter can be in any arrangement, size shape, and/or number, to create preferable flow conditions through the catheter.

[0053] While various embodiments have been described above, it should be understood that they have been presented by way of example only, and not limitation. Where methods and/or schematics described above indicate certain events and/or flow patterns occurring in certain order, the ordering of certain events and/or flow patterns may be modified. Additionally certain events may be performed concurrently in parallel processes when possible, as well as performed sequentially. While various embodiments have been described as having particular features and/or combinations of components, other embodiments are possible having a combination of any features and/or components from any of embodiments as discussed above.

What is claimed:

1. An apparatus, comprising:

an introducer coupleable to a peripheral intravenous line, the peripheral intravenous line being at least partially insertable into a vein of a patient; and

a catheter movable from a first position inside the introducer and outside the peripheral intravenous line to a second position at least partially outside the introducer and extending through the peripheral intravenous line, a proximal end of the catheter disposed in the introducer when the catheter is in the first position and the second position.

2. The apparatus of claim **1**, further comprising:

an actuator coupled to the proximal end portion of the catheter and movable along a fixed length of the introducer to move the catheter between the first position and the second position.

3. The apparatus of claim **2**, wherein the introducer defines a slot, the actuator being movable within the slot along the fixed length of the introducer.

4. The apparatus of claim **1**, wherein the introducer is configured to transition between a first configuration and a second configuration to move the catheter between the first position and the second position.

5. The apparatus of claim **4**, wherein the introducer has a first length when in the first configuration and a second length less than the first length when in the second configuration.

6. The apparatus of claim **4**, wherein at least a portion of the introducer is collapsible from the first configuration to the second configuration.

7. The apparatus of claim **1**, further comprising:

an adapter coupleable between a lock at a distal end portion of the introducer and at least one of a first port or a second port of the peripheral intravenous line.

8. The apparatus of claim **7**, wherein the lock of the introducer is coupleable to one of a first port and a second port of the adapter, the catheter in the second position extendable through the adapter and the peripheral intravenous line such that a distal end of the catheter is distal to the peripheral intravenous line when the adapter is coupled between the lock of the introducer and the peripheral intravenous line.

9. An apparatus, comprising:

an introducer coupleable to a peripheral intravenous line, the peripheral intravenous line being at least partially insertable into a vein of a patient; and

a catheter movable between a first position inside the introducer and proximal to the peripheral intravenous line and a second position at least partially outside the introducer such that a distal end of the catheter is distal to the peripheral intravenous line, a proximal end of the catheter disposed in the introducer and proximal to the peripheral intravenous line when the catheter is in the second position.

10. The apparatus of claim **9**, further comprising:

an actuator coupled to the proximal end portion of the catheter and movable along a fixed length of the introducer to move the catheter between the first position and the second position.

11. The apparatus of claim **10**, wherein the introducer defines a slot, the actuator being movable within the slot along the fixed length of the introducer.

12. The apparatus of claim **9**, wherein a distal end portion of the introducer includes a lock that is coupleable to one of a first port and a second port of the peripheral intravenous line.

13. The apparatus of claim **9**, further comprising:

an adapter coupleable between a lock at a distal end portion of the introducer and at least one of a first port or a second port of the peripheral intravenous line.

14. The apparatus of claim **13**, wherein the catheter in the second position is extendable through the adapter and the peripheral intravenous line when the adapter is coupled between the lock of the introducer and the peripheral intravenous line such that (i) a distal end of the catheter is distal to the peripheral intravenous line and (ii) a proximal end of catheter is disposed in the introducer and proximal to the adapter.

15. An apparatus, comprising:

an introducer coupleable to an adapter connected to a port of a peripheral intravenous line that is at least partially insertable into a vein of a patient; and

a catheter movable between a first position inside the introducer and proximal to the adapter and a second position partially outside the introducer, a portion of the catheter in the second position extendable through the adapter and the peripheral intravenous line to place a distal end of the catheter distal to the peripheral intravenous line, a proximal end of the catheter in the second position disposed in the introducer and proximal to the adapter.

16. The apparatus of claim **15**, further comprising:

an actuator coupled to the proximal end portion of the catheter and movable along a fixed length of the introducer to move the catheter between the first position and the second position.

17. The apparatus of claim **16**, wherein the introducer defines a slot, the actuator being movable within the slot along the fixed length of the introducer.

18. The apparatus of claim **15**, wherein the introducer is configured to transition between a first configuration and a second configuration to move the catheter between the first position and the second position.

19. The apparatus of claim **18**, wherein the introducer has a first length when in the first configuration and a second length less than the first length when in the second configuration.

20. The apparatus of claim **15**, wherein the port of the peripheral intravenous line is a first port, the peripheral intravenous line including a second port, the adapter being connectable to one of the first port and the second port.

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