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(12) **United States Patent**
Rogers et al.

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(45) **Date of Patent: *Jul. 3, 2018**

(54) **BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD**

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(73) Assignee: **KURIN, INC.**, San Diego, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 253 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **15/140,448**

(22) Filed: **Apr. 27, 2016**

(65) **Prior Publication Data**

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Related U.S. Application Data

(60) Provisional application No. 62/196,797, filed on Jul. 24, 2015, provisional application No. 62/238,636, (Continued)

(51) **Int. Cl.**
A61B 5/00 (2006.01)
B65D 81/00 (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC ***A61B 5/150992*** (2013.01); ***A61B 5/15003*** (2013.01); ***A61B 5/153*** (2013.01); ***A61B 5/154*** (2013.01); ***A61B 5/150213*** (2013.01); ***A61B 5/150221*** (2013.01); ***A61B 5/150389*** (2013.01); ***A61B 5/150473*** (2013.01); ***A61B 5/150572*** (2013.01); ***A61M 39/04*** (2013.01); ***A61M 39/0693*** (2013.01); *A61M 2039/0202* (2013.01);
(Continued)

(58) **Field of Classification Search**
CPC A61B 10/0096; A61B 5/150022
USPC 600/573, 583; 604/164.01; 435/294.1
See application file for complete search history.

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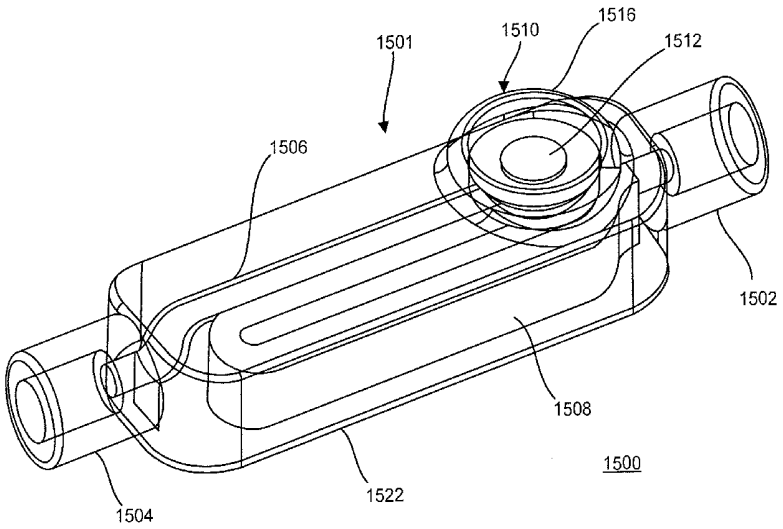
Primary Examiner — May Abouelela
(74) *Attorney, Agent, or Firm* — Troutman Sanders, LLP

(57) **ABSTRACT**

Blood sample optimization systems and methods are described that reduce or eliminate contaminates in collected blood samples, which in turn reduces or eliminates false positive readings in blood cultures or other testing of collected blood samples. A blood sample optimization system can include a blood sequestration device located between a patient needle and a sample needle. The blood sequestration device can include a sequestration chamber for sequestering an initial, potentially contaminated aliquot of blood, and may further include a sampling channel that bypasses the sequestration chamber to convey likely uncontaminated blood between the patient needle and the sample needle after the initial aliquot of blood is sequestered in the sequestration chamber.

16 Claims, 50 Drawing Sheets



Related U.S. Application Data

filed on Oct. 7, 2015, provisional application No. 62/318,194, filed on Apr. 4, 2016.

(51) **Int. Cl.**

A61B 5/15	(2006.01)
A61M 39/04	(2006.01)
A61B 5/153	(2006.01)
A61B 5/154	(2006.01)
A61M 39/02	(2006.01)
A61M 39/06	(2006.01)

(52) **U.S. Cl.**

CPC *A61M 2039/068* (2013.01); *A61M 2039/0633* (2013.01)

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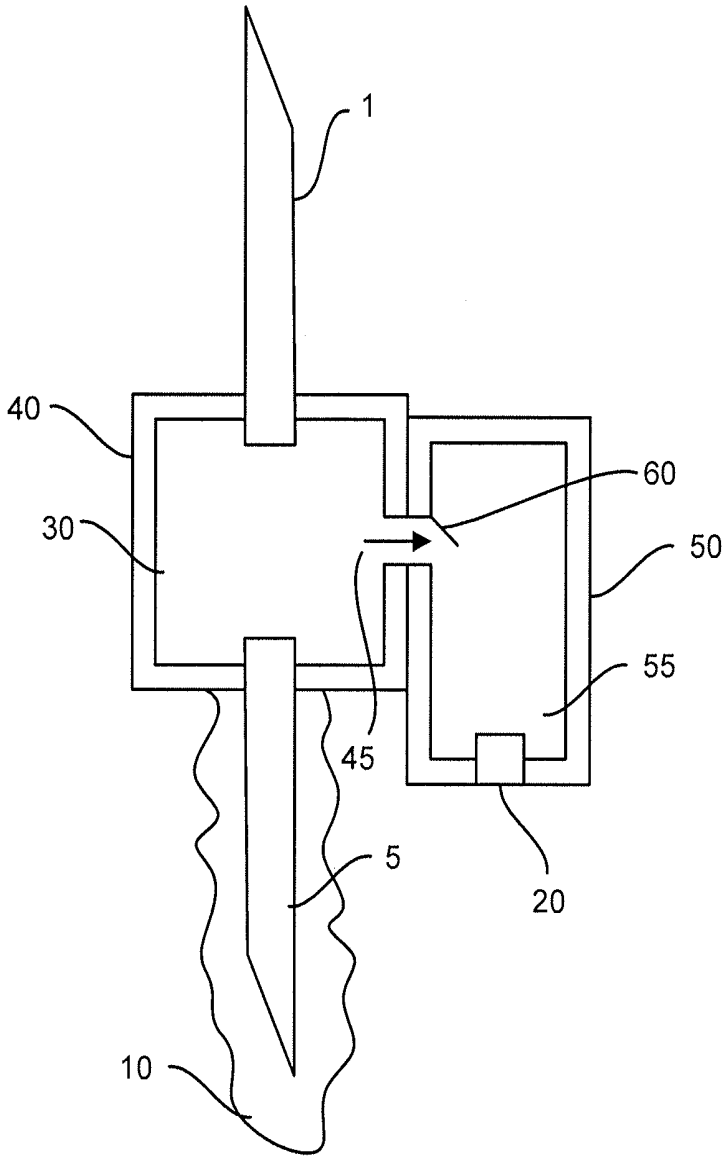

FIG. 1

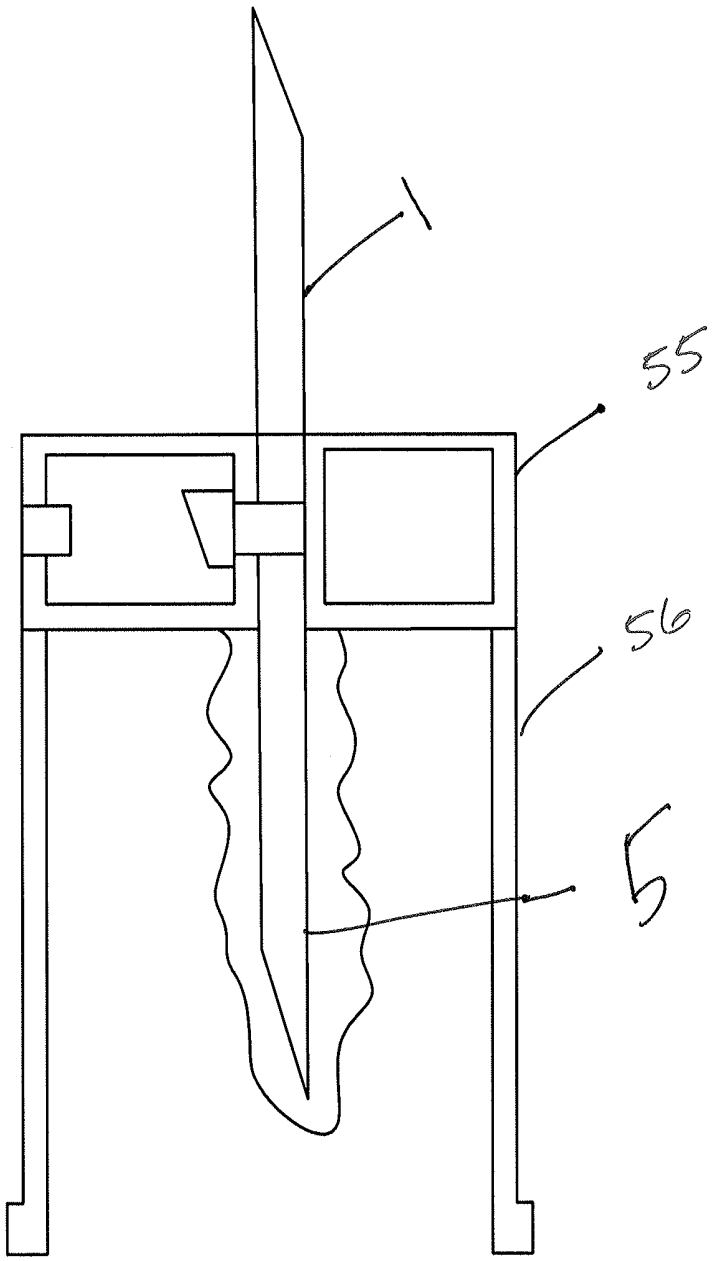

FIG. 2

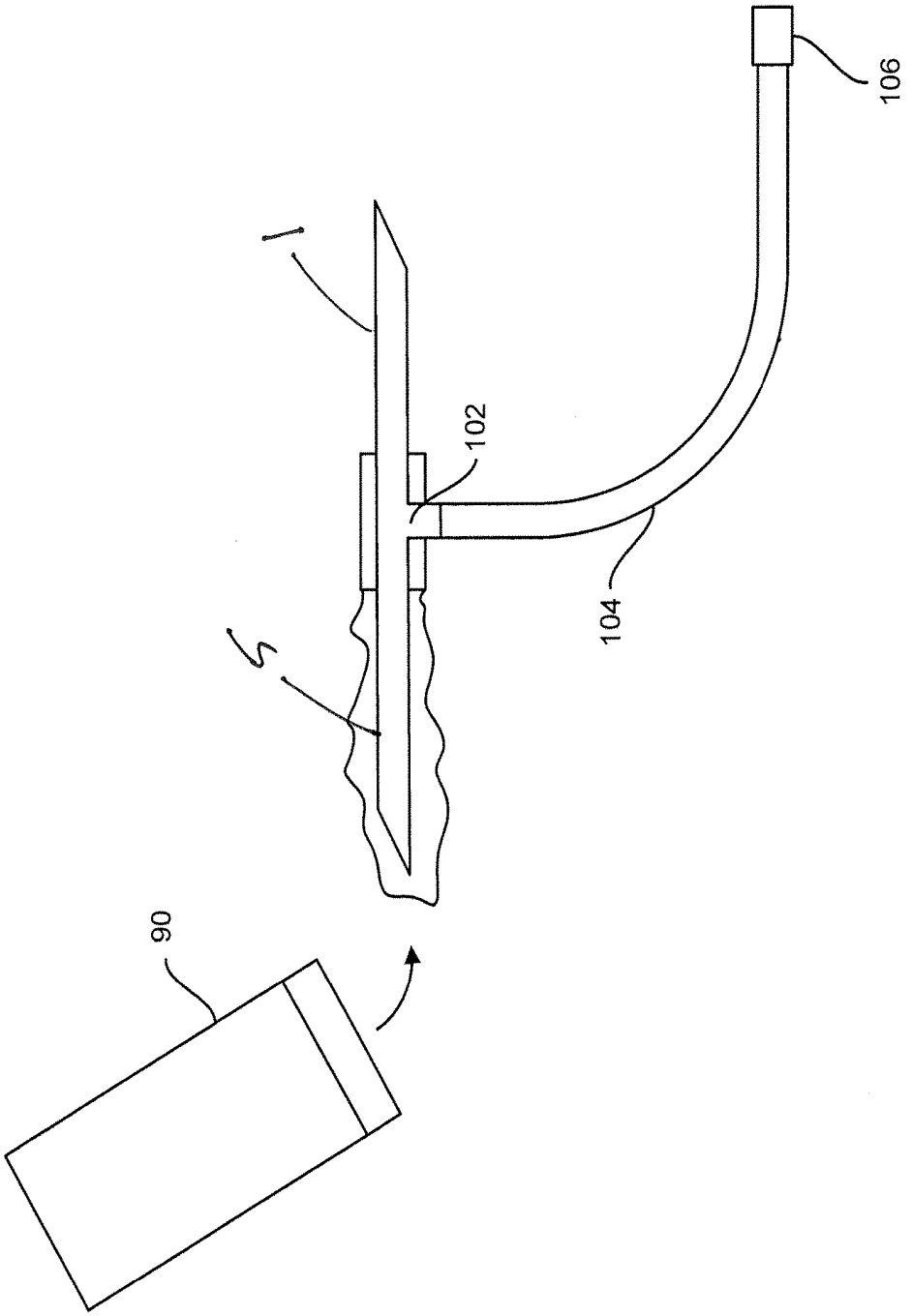

FIG. 3

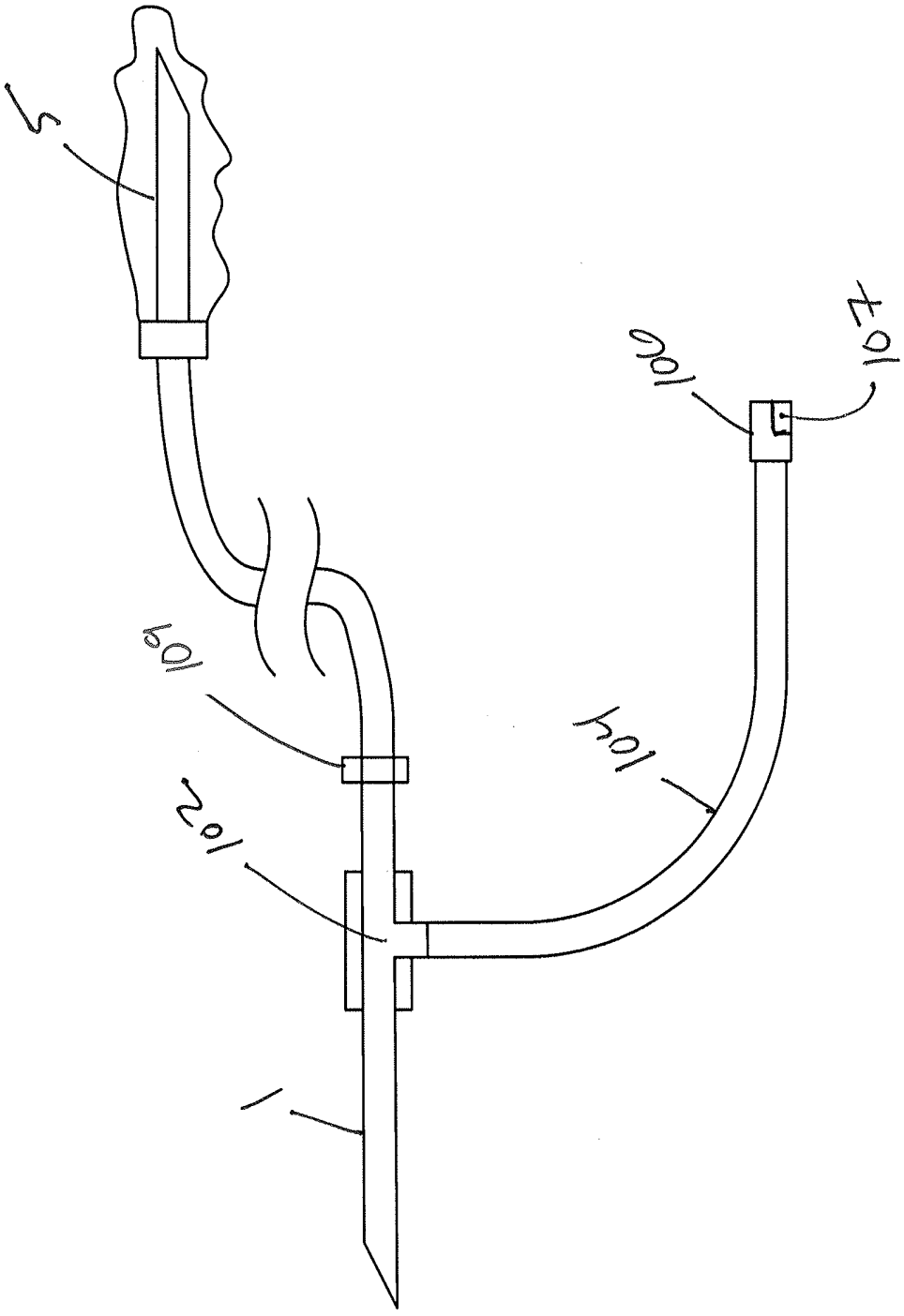

FIG. 4

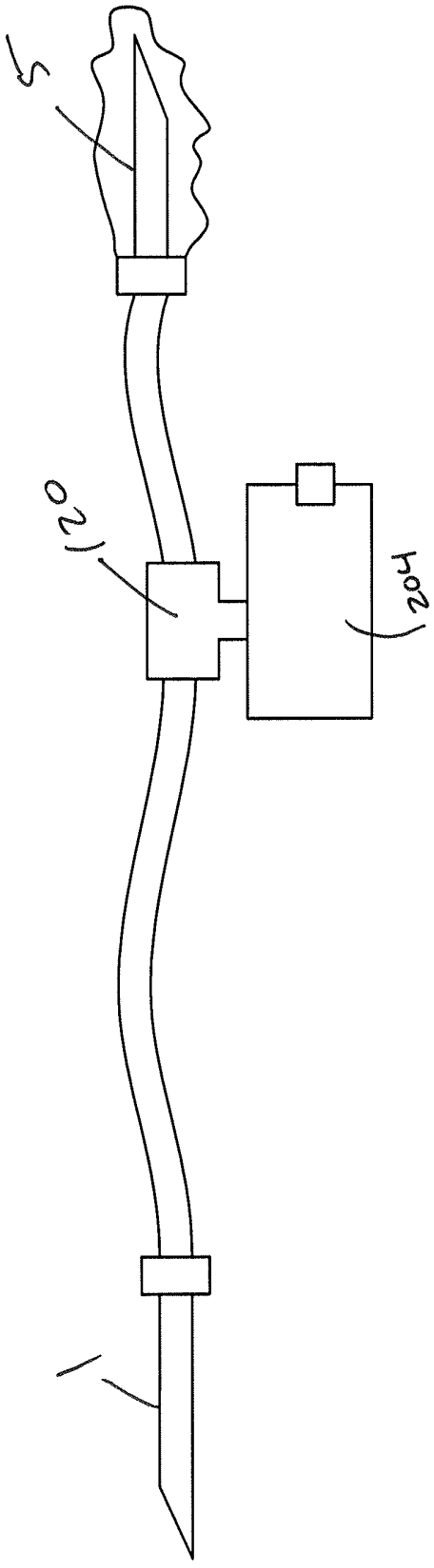

FIG. 5

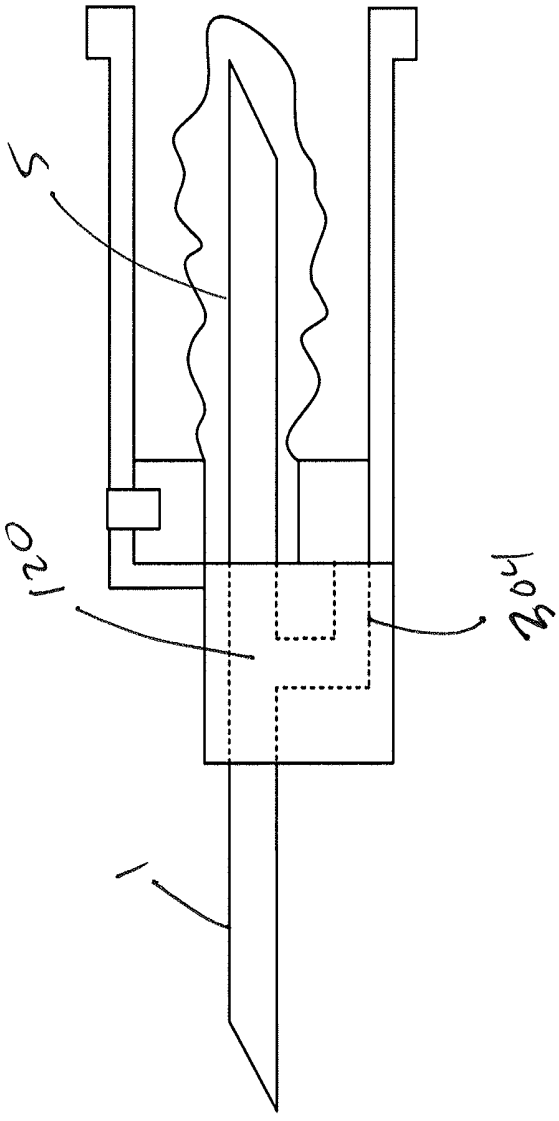

FIG. 6

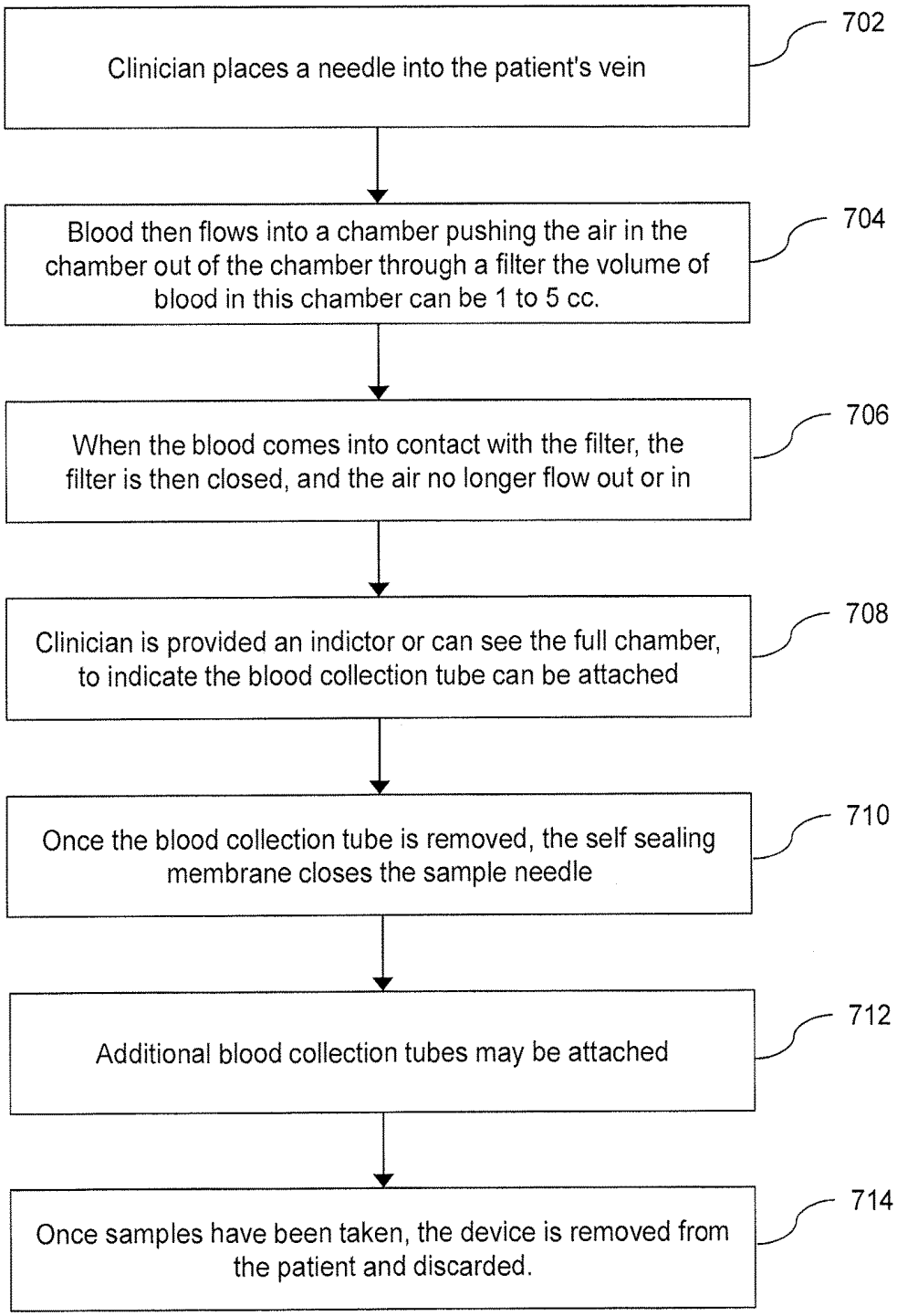
Clinician places a needle into the patient's vein
702
Blood then flows into a chamber pushing the air in the chamber out of the chamber through a filter the volume of blood in this chamber can be 1 to 5 cc.
704
When the blood comes into contact with the filter, the filter is then closed, and the air no longer flow out or in
706
Clinician is provided an indictor or can see the full chamber, to indicate the blood collection tube can be attached
708
Once the blood collection tube is removed, the self sealing membrane closes the sample needle
710
Additional blood collection tubes may be attached
712
Once samples have been taken, the device is removed from the patient and discarded.
714

FIG. 7

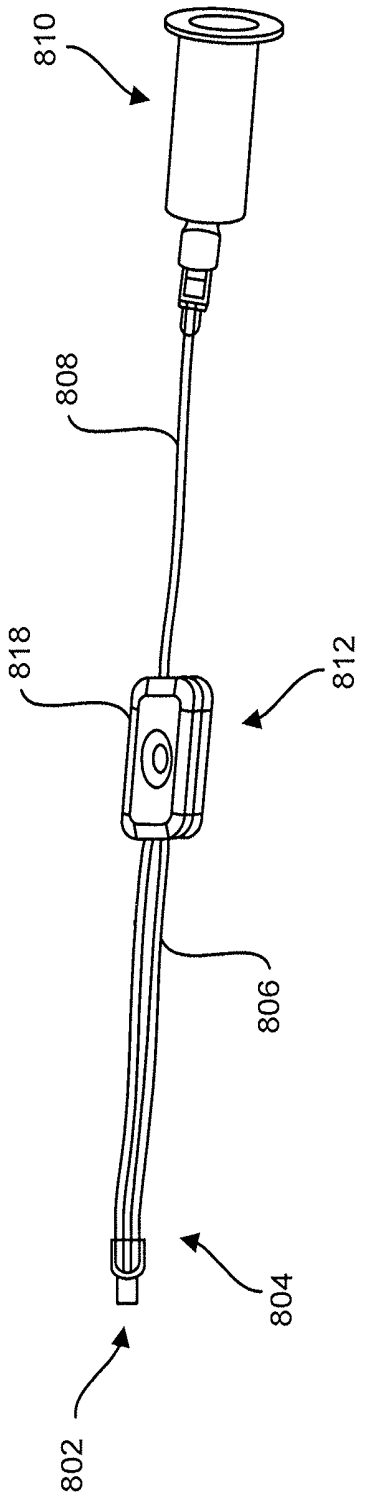

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FIG. 8A

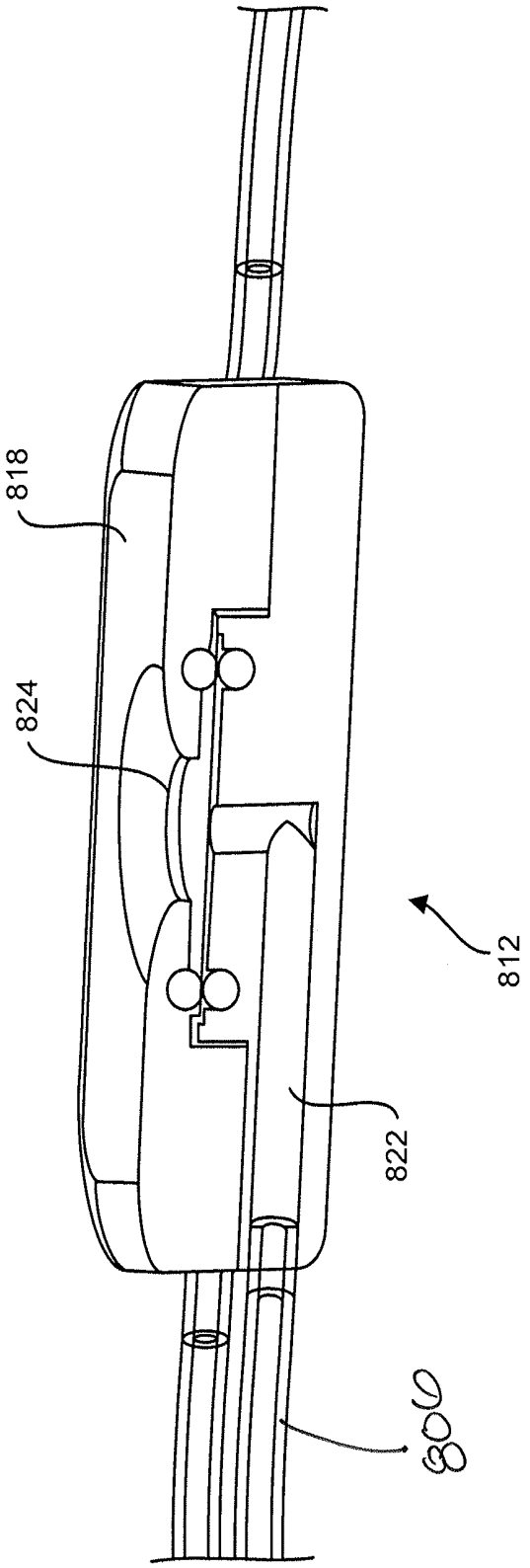


FIG. 8B

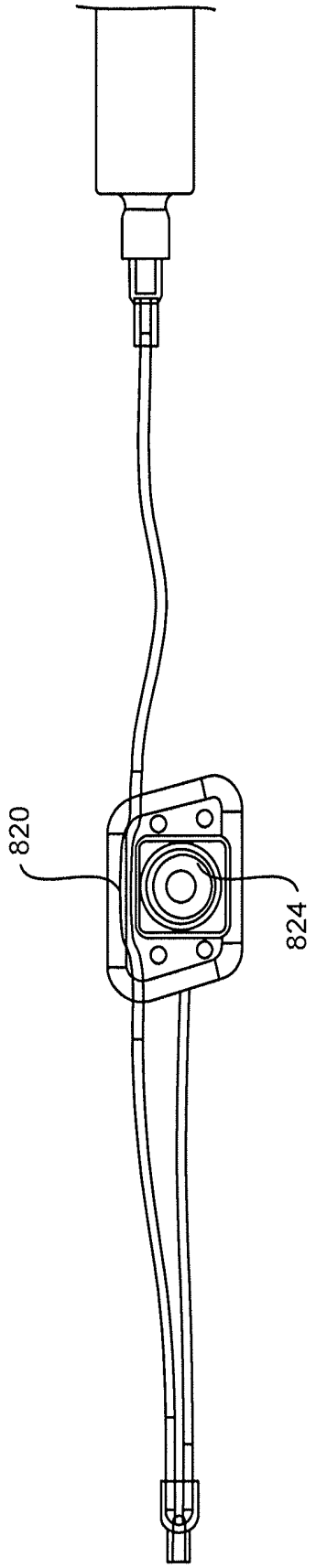


FIG. 8C

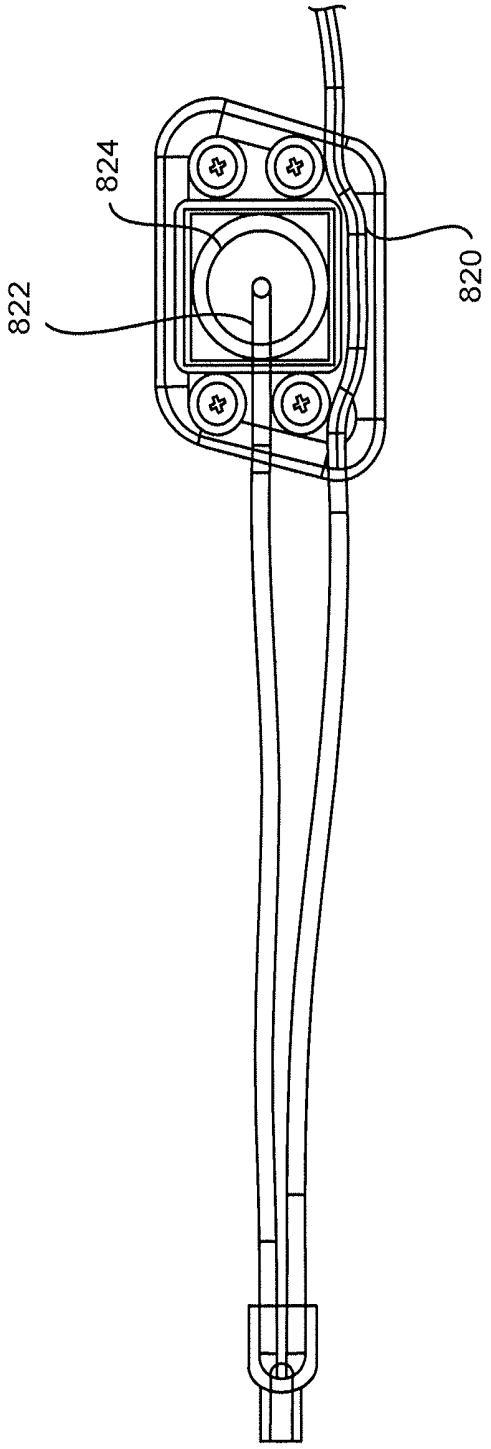


FIG. 8D

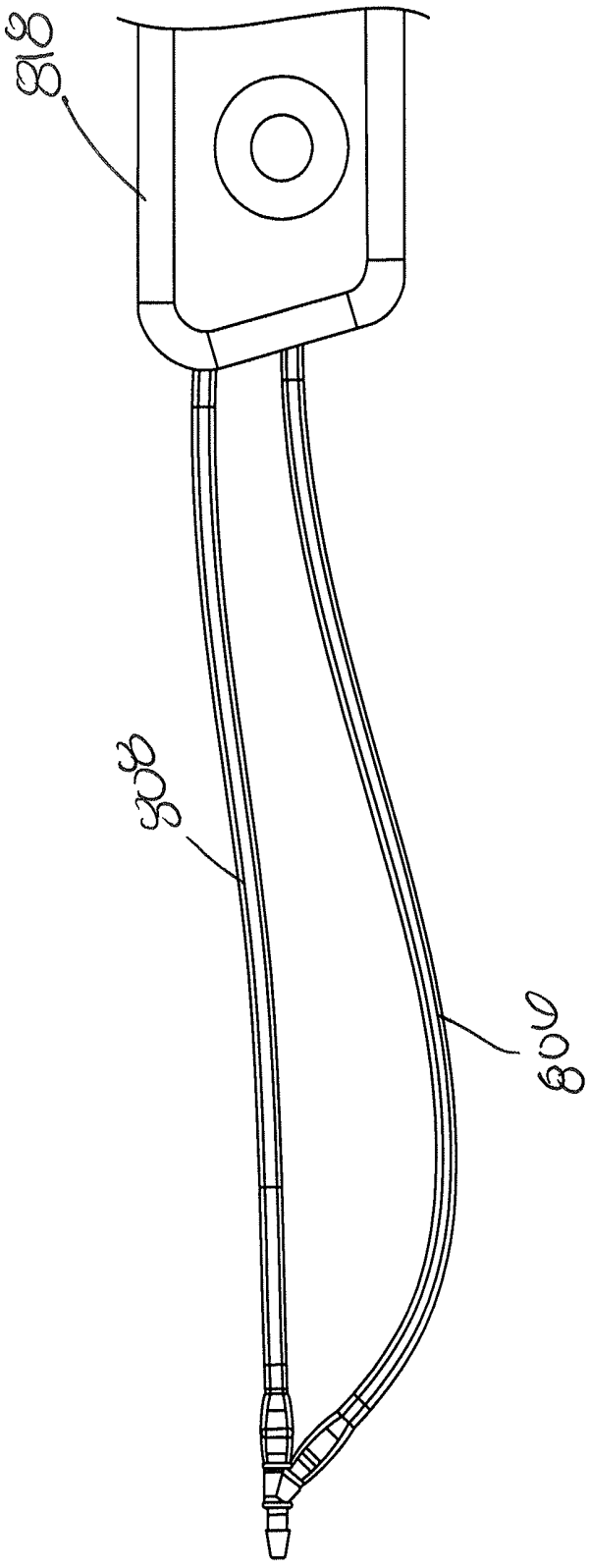


FIG. 8E

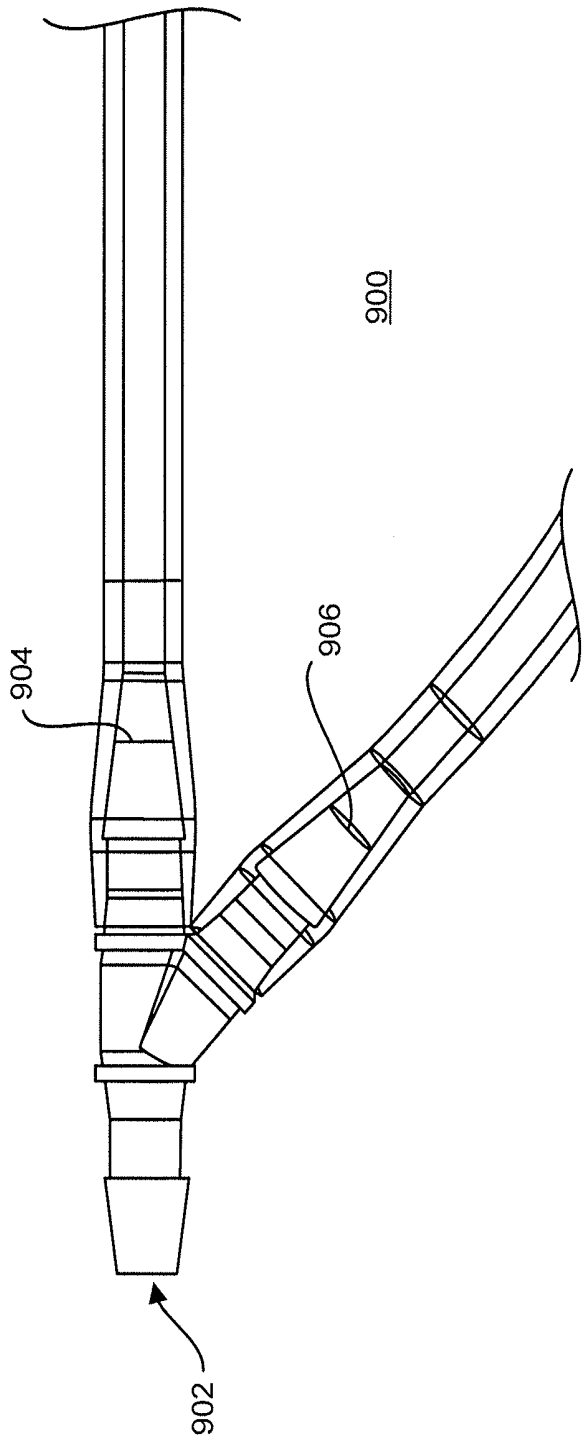


FIG. 9

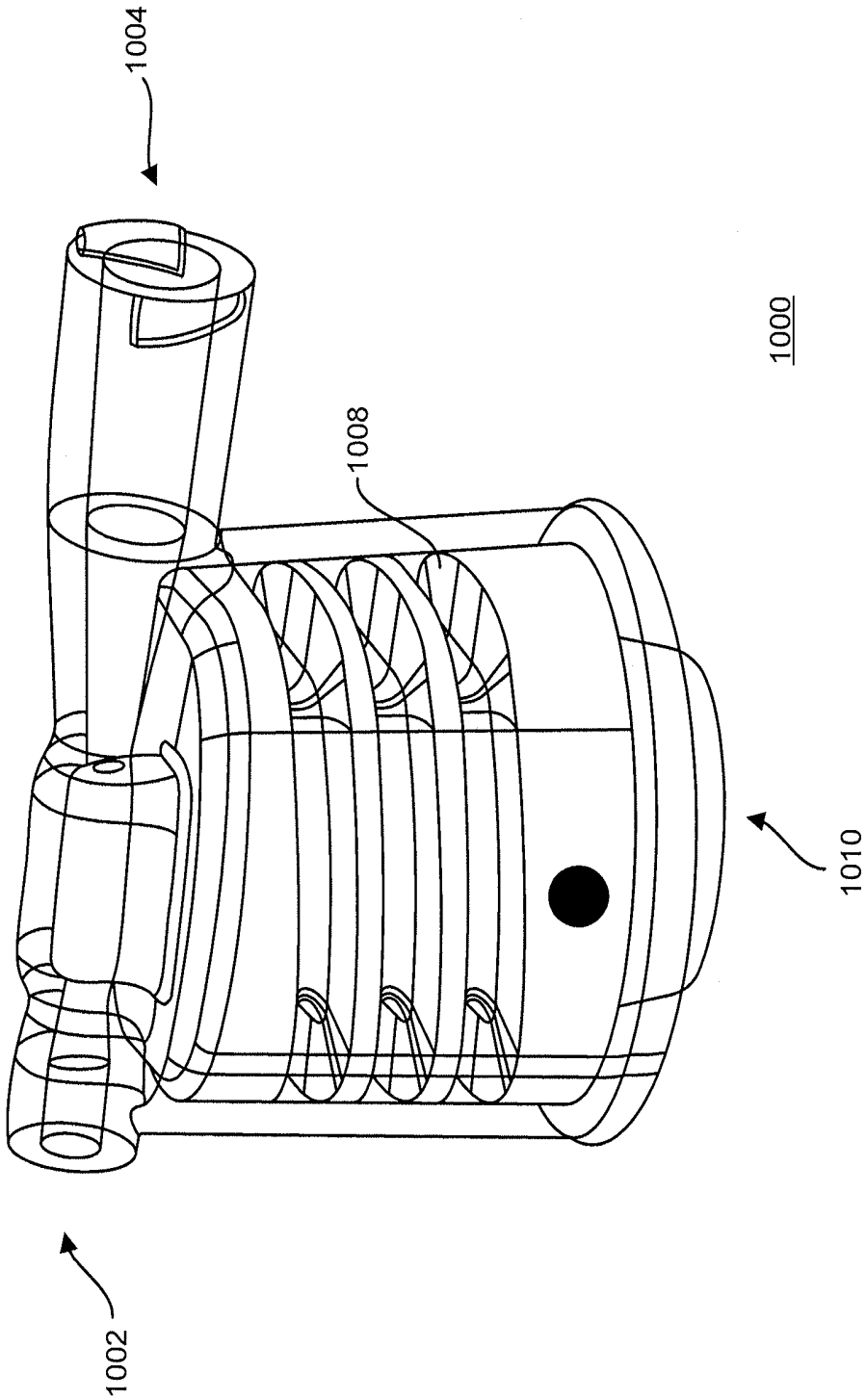


FIG. 10A

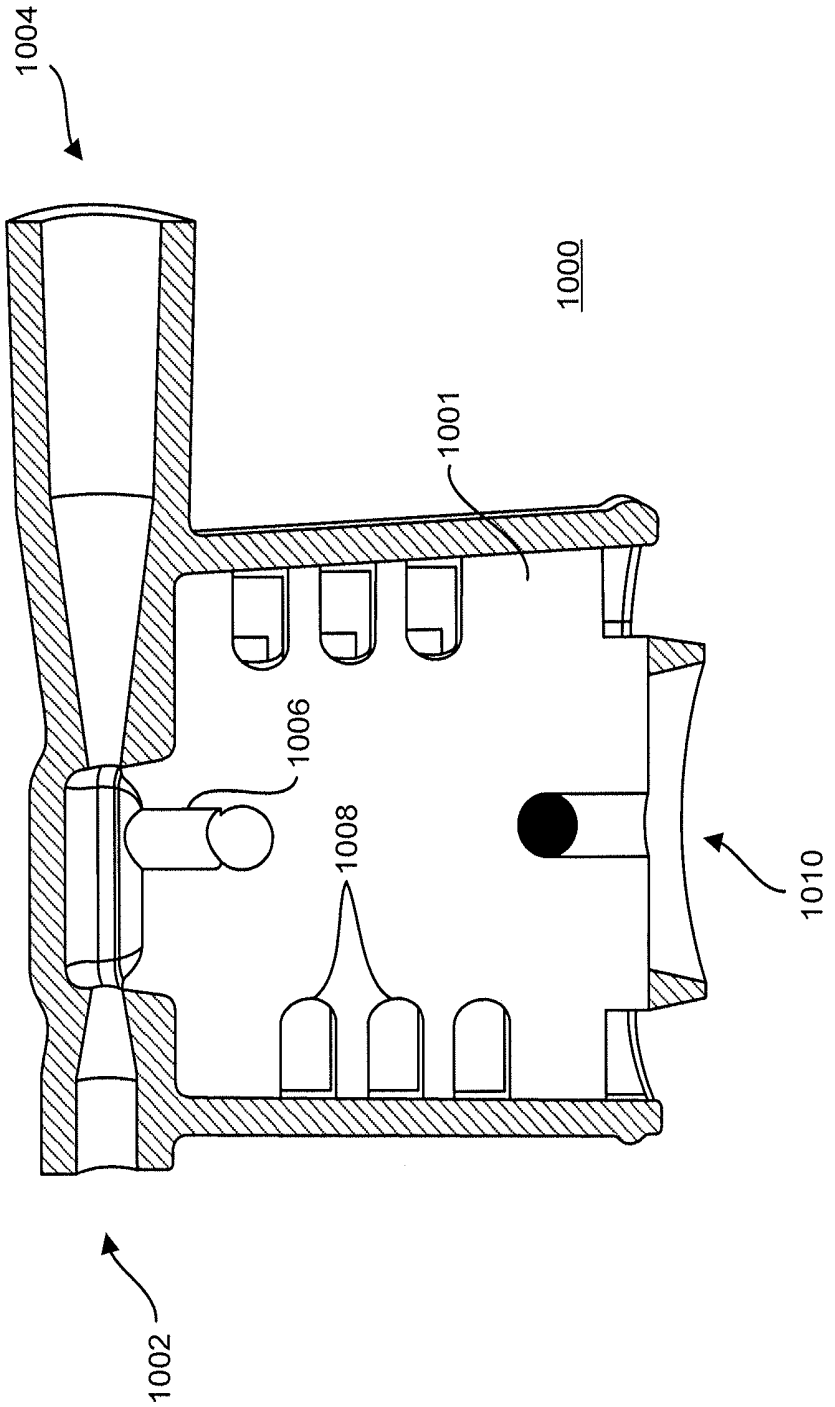


FIG. 10B

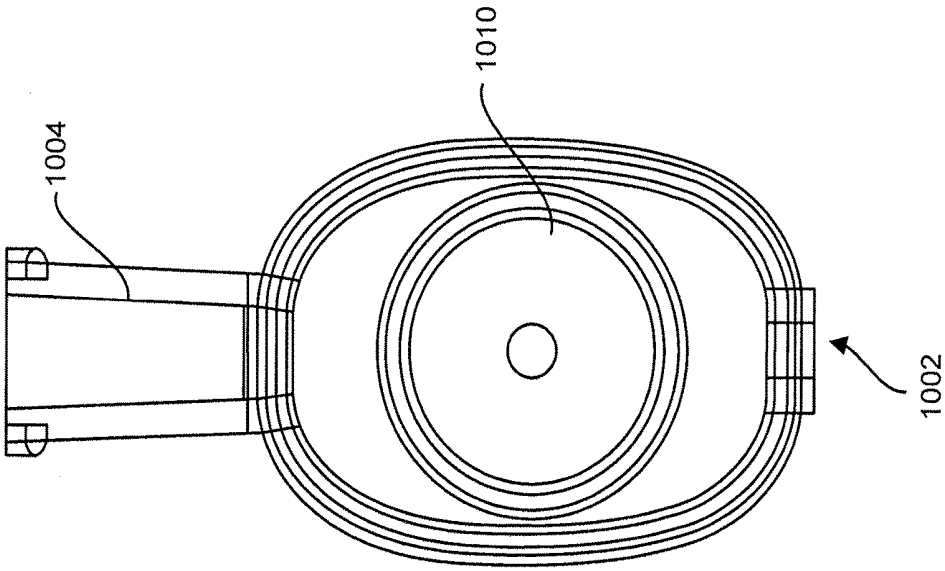


FIG. 10C

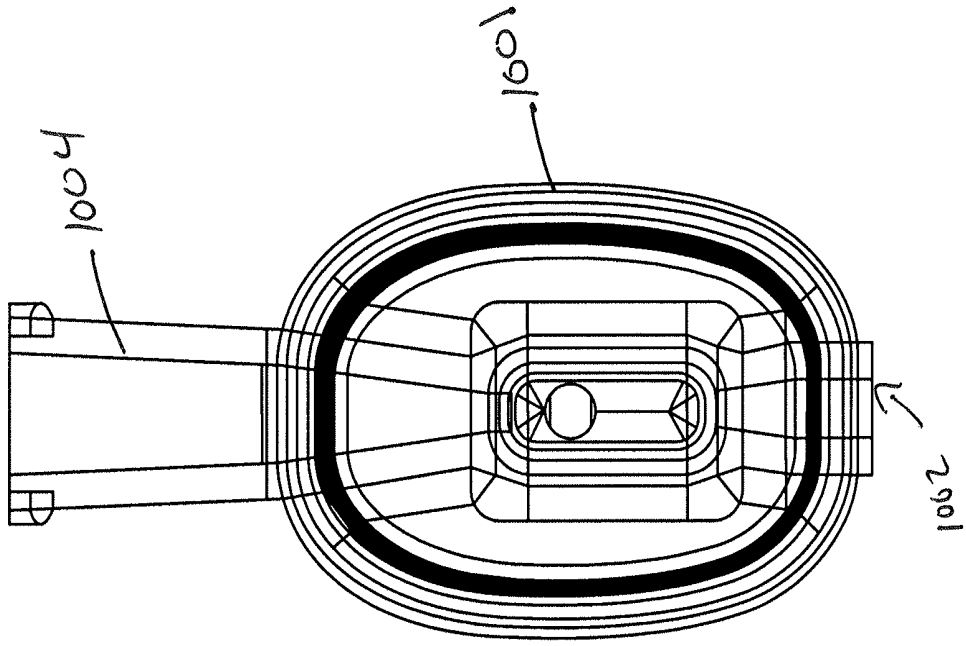


FIG. 10D

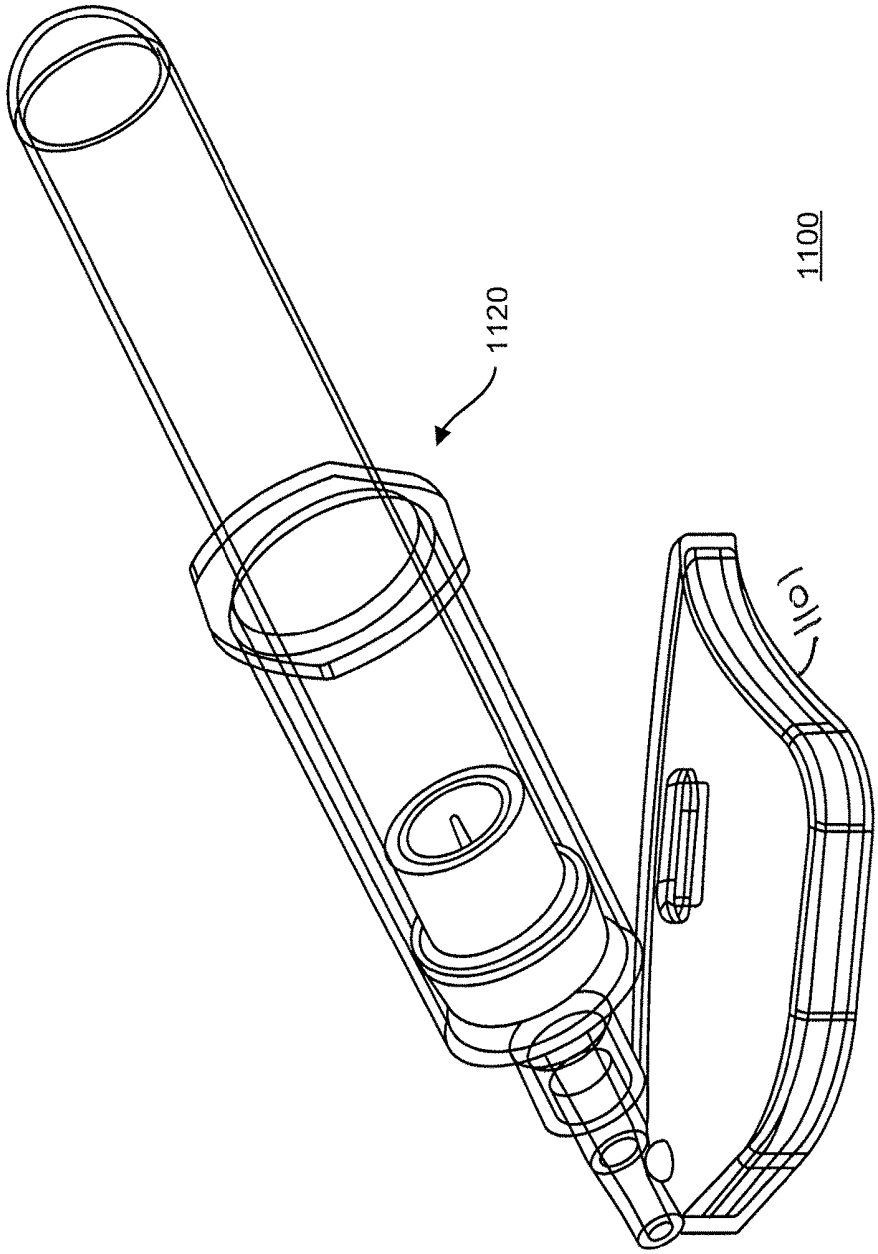


FIG. 11A

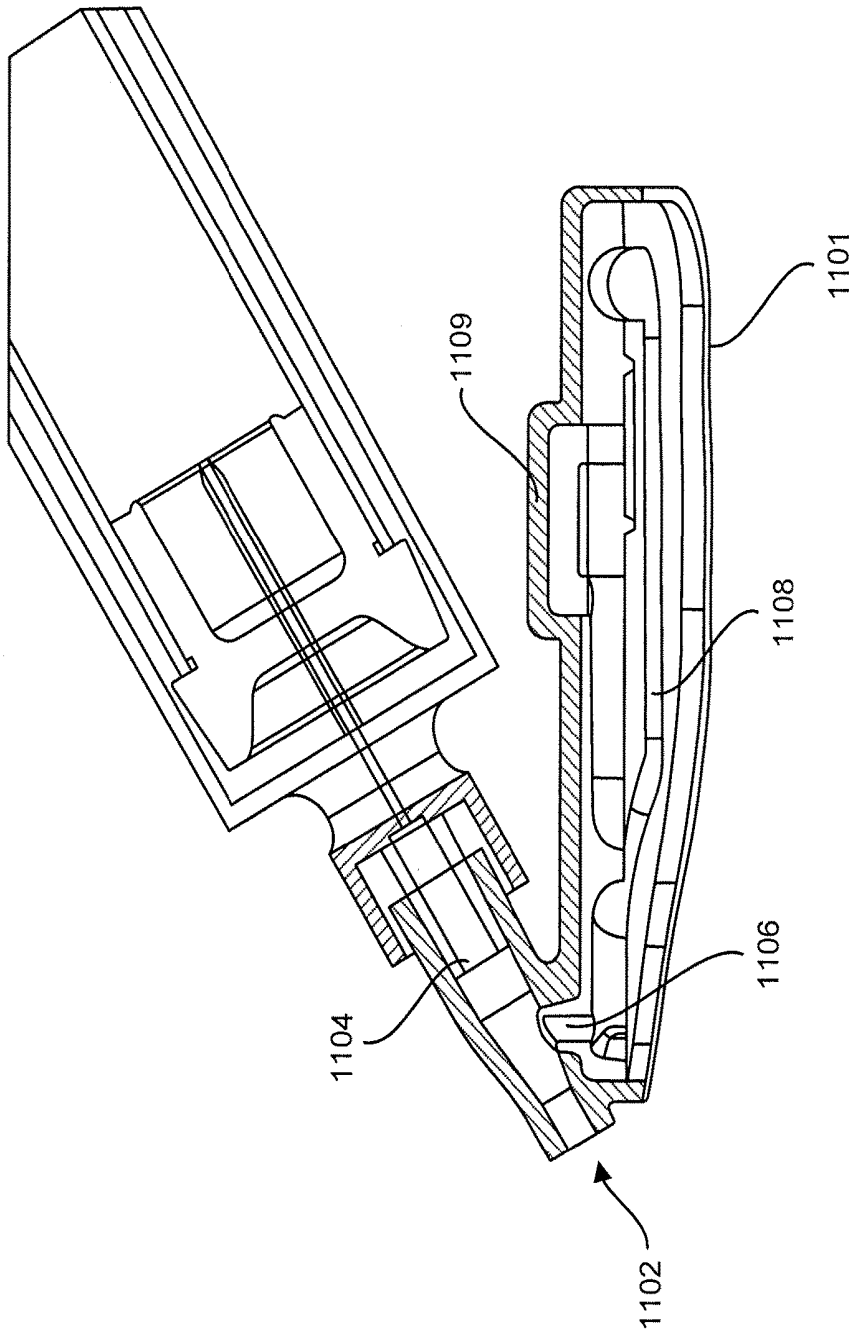


FIG. 11B

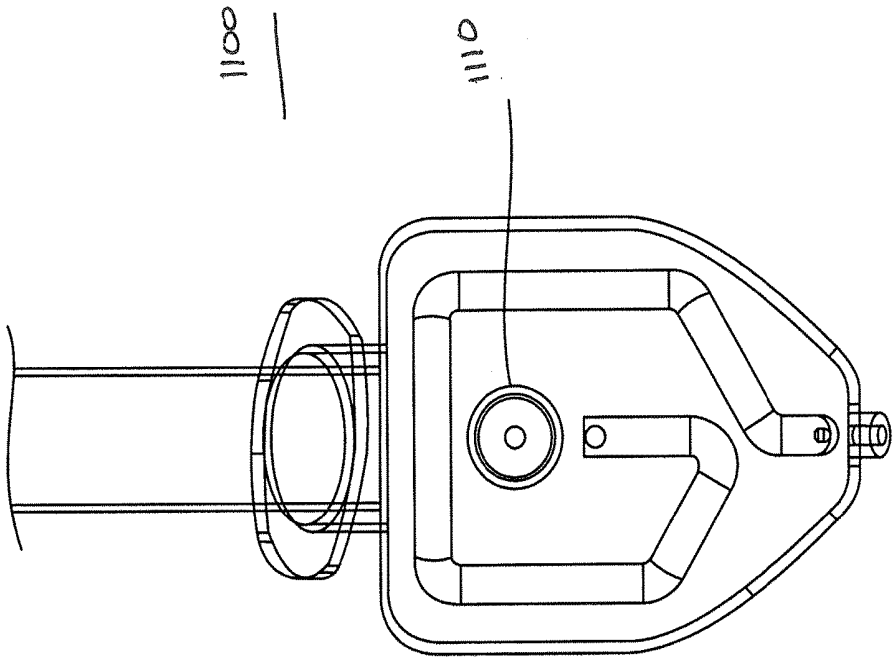


FIG. 11C

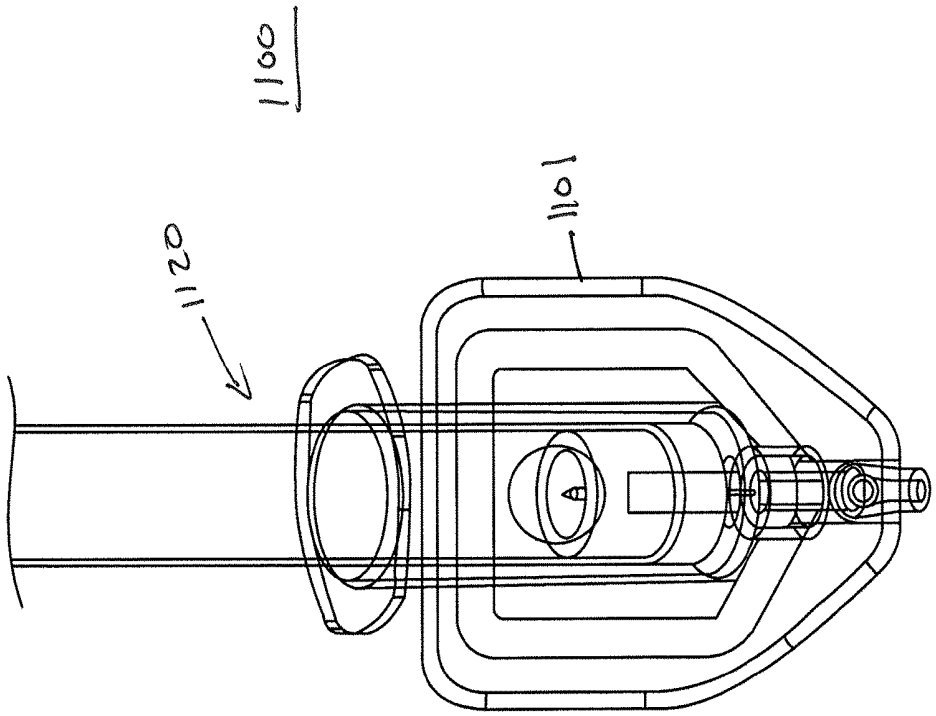


FIG. 11D

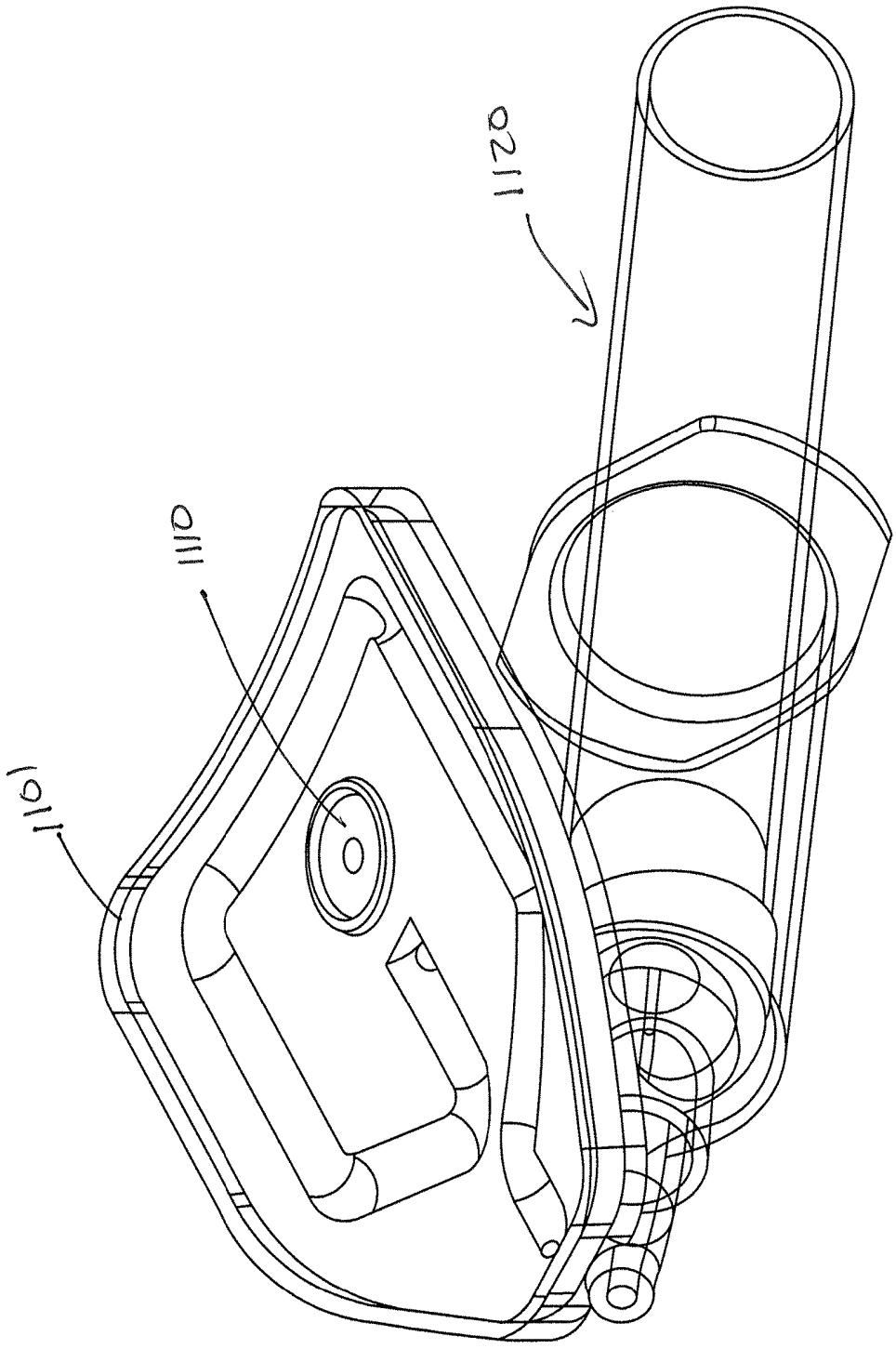


FIG. 11E

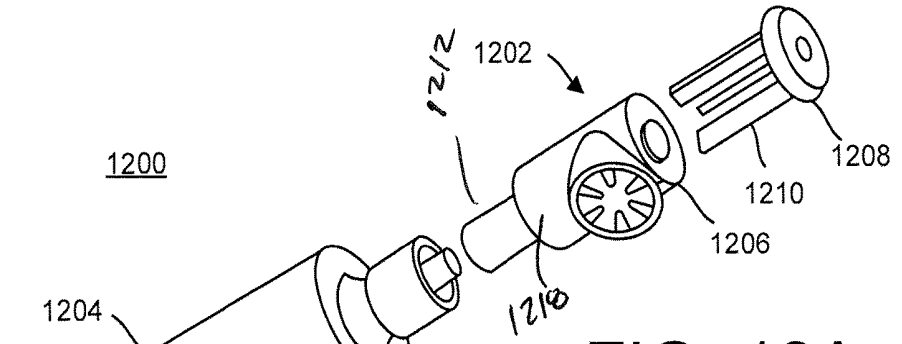


FIG. 12A

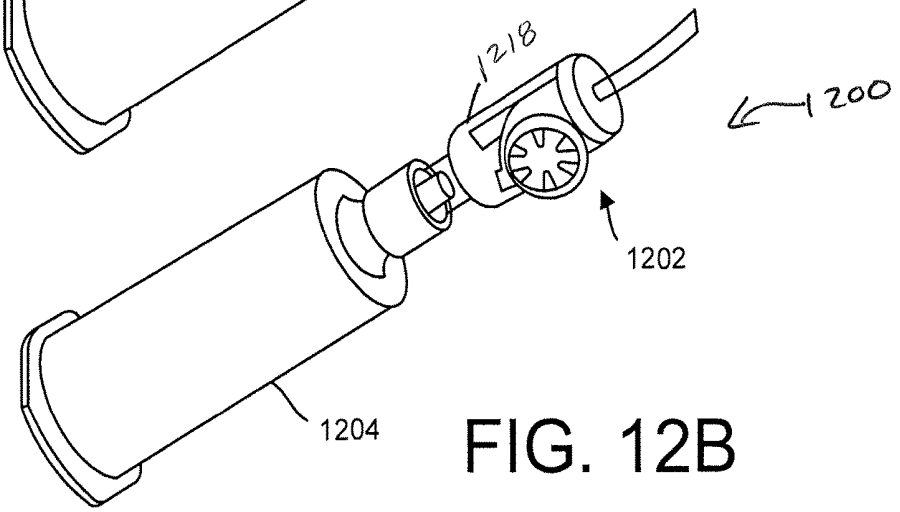


FIG. 12B

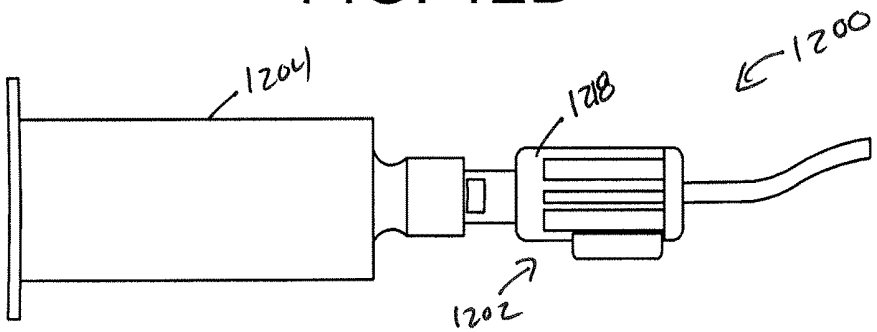


FIG. 12C

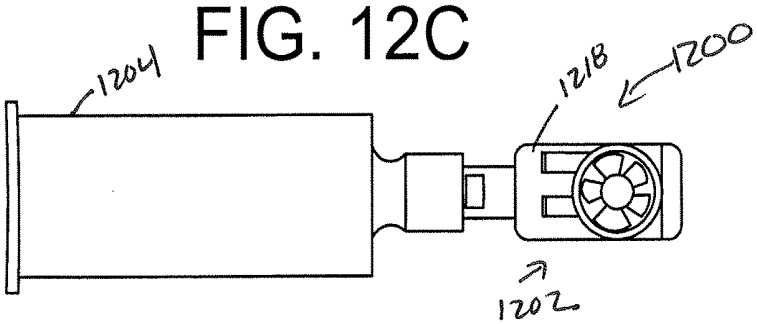


FIG. 12D

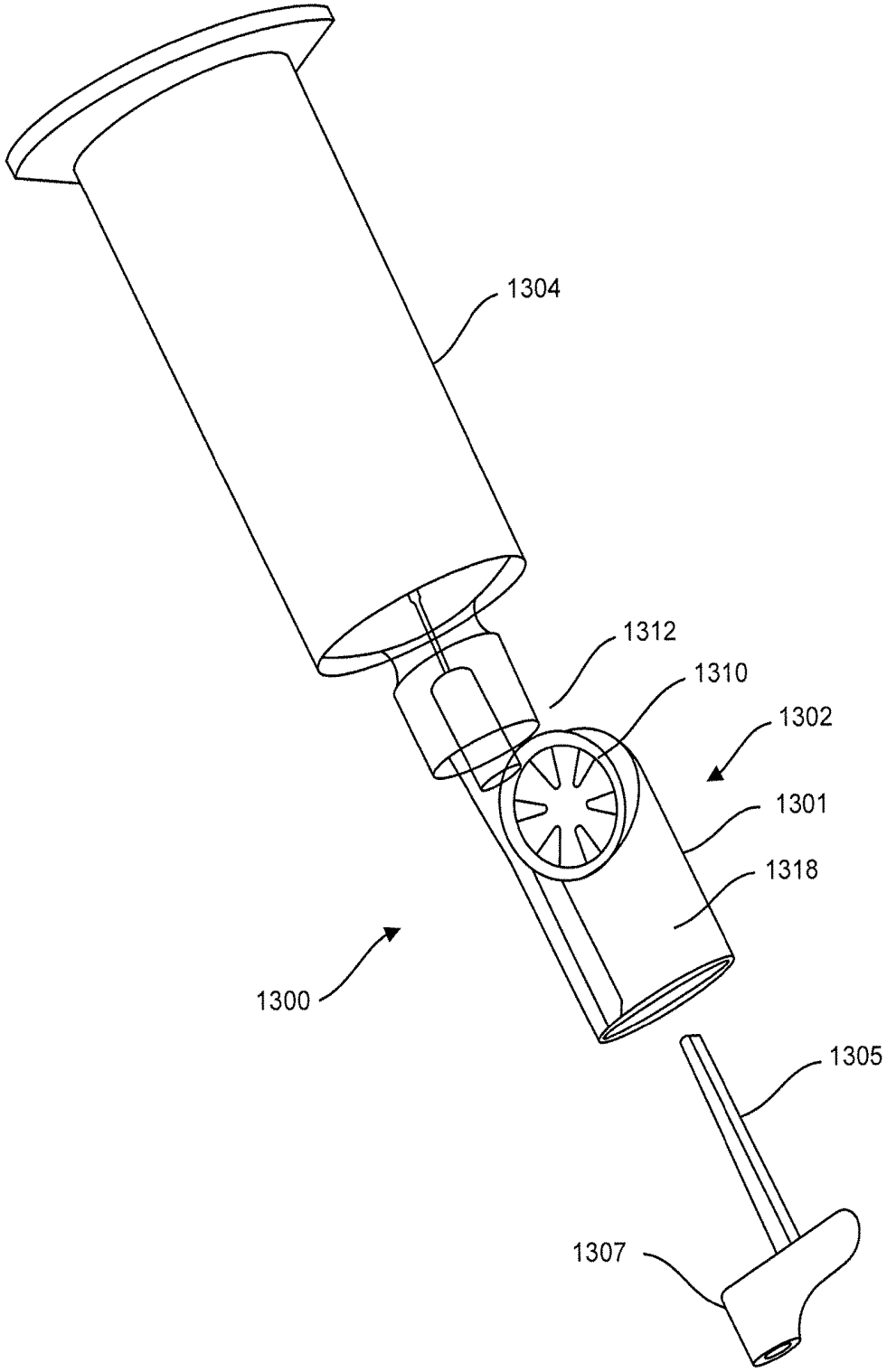


FIG. 13A

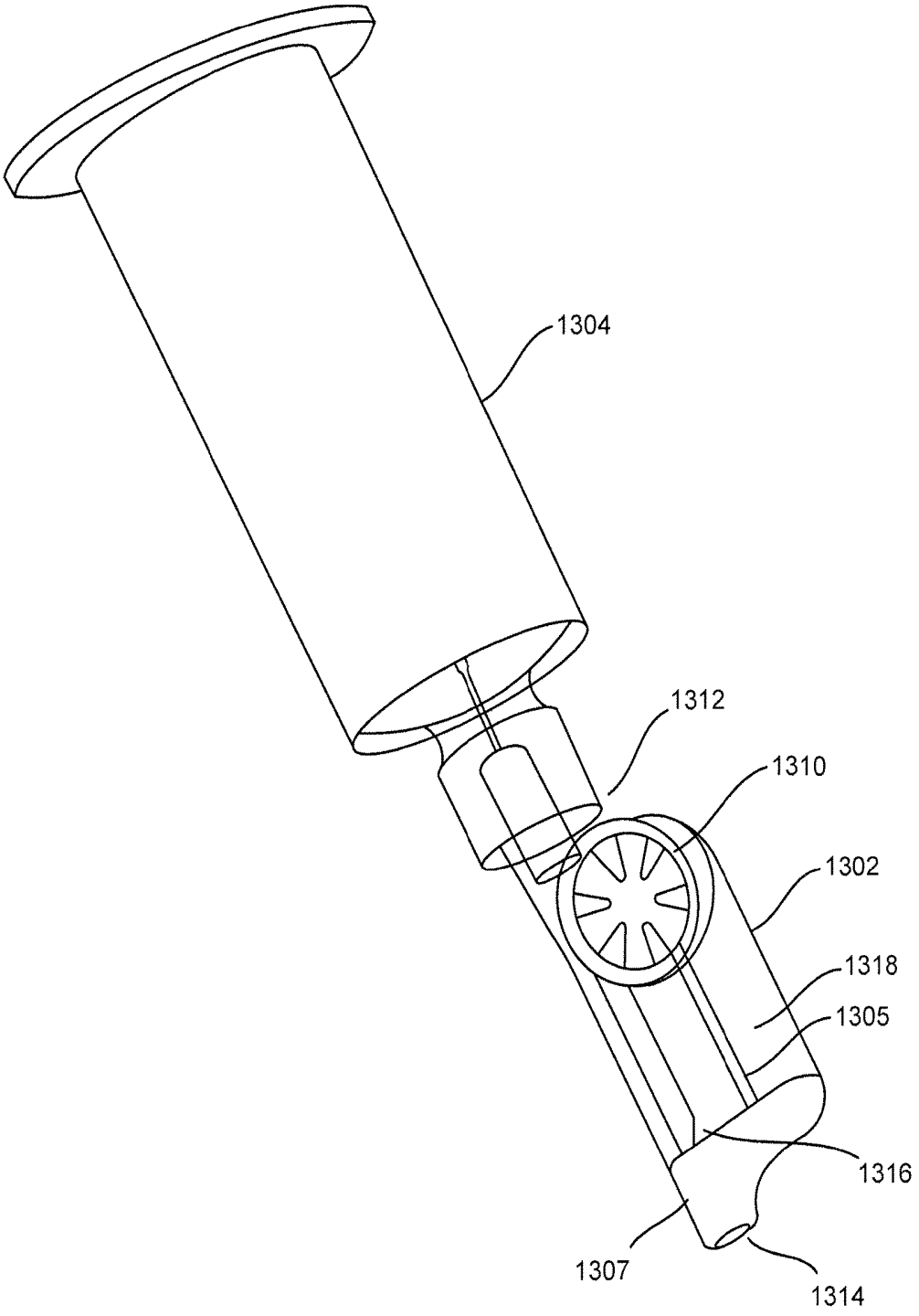


FIG. 13B

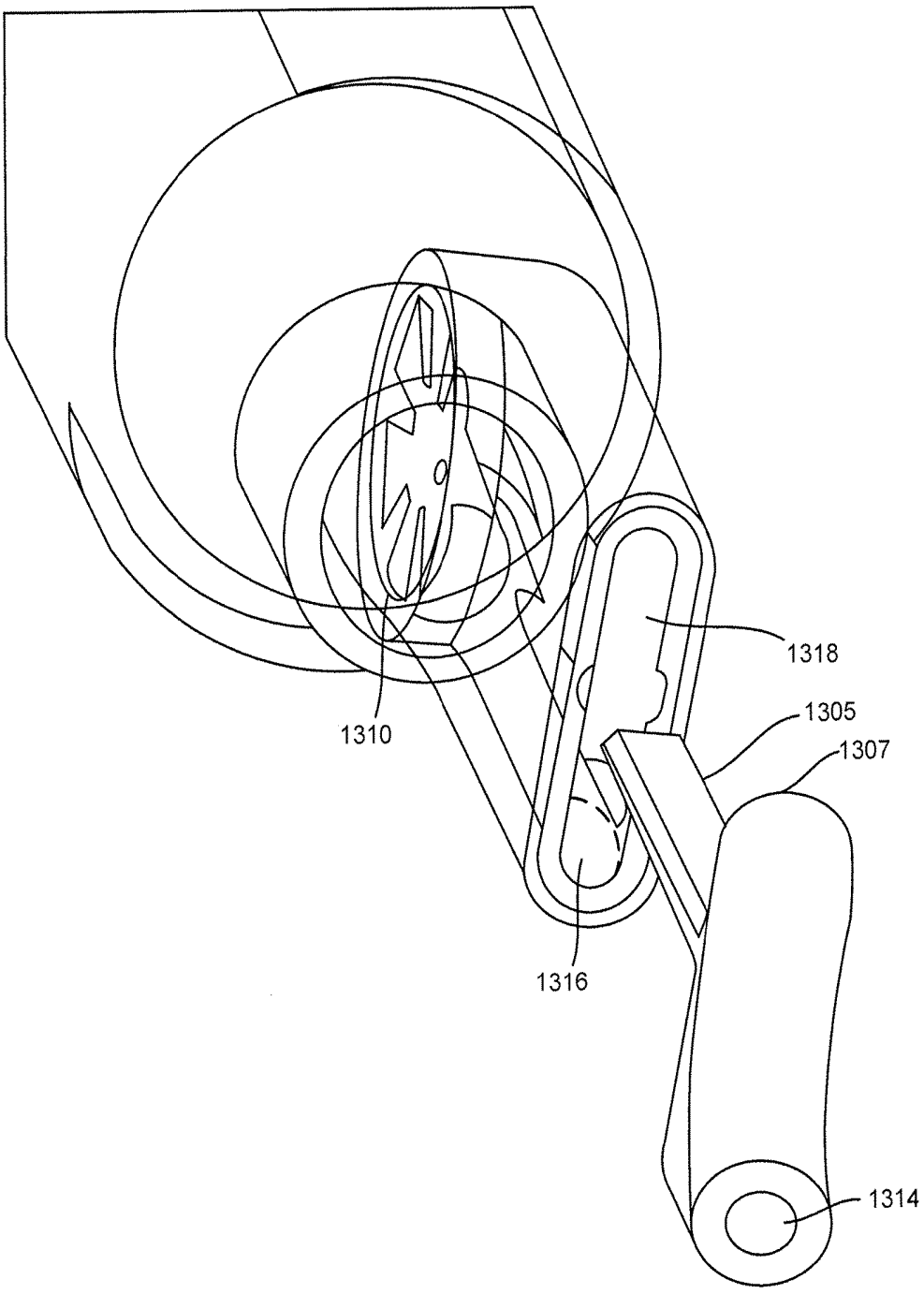


FIG. 13C

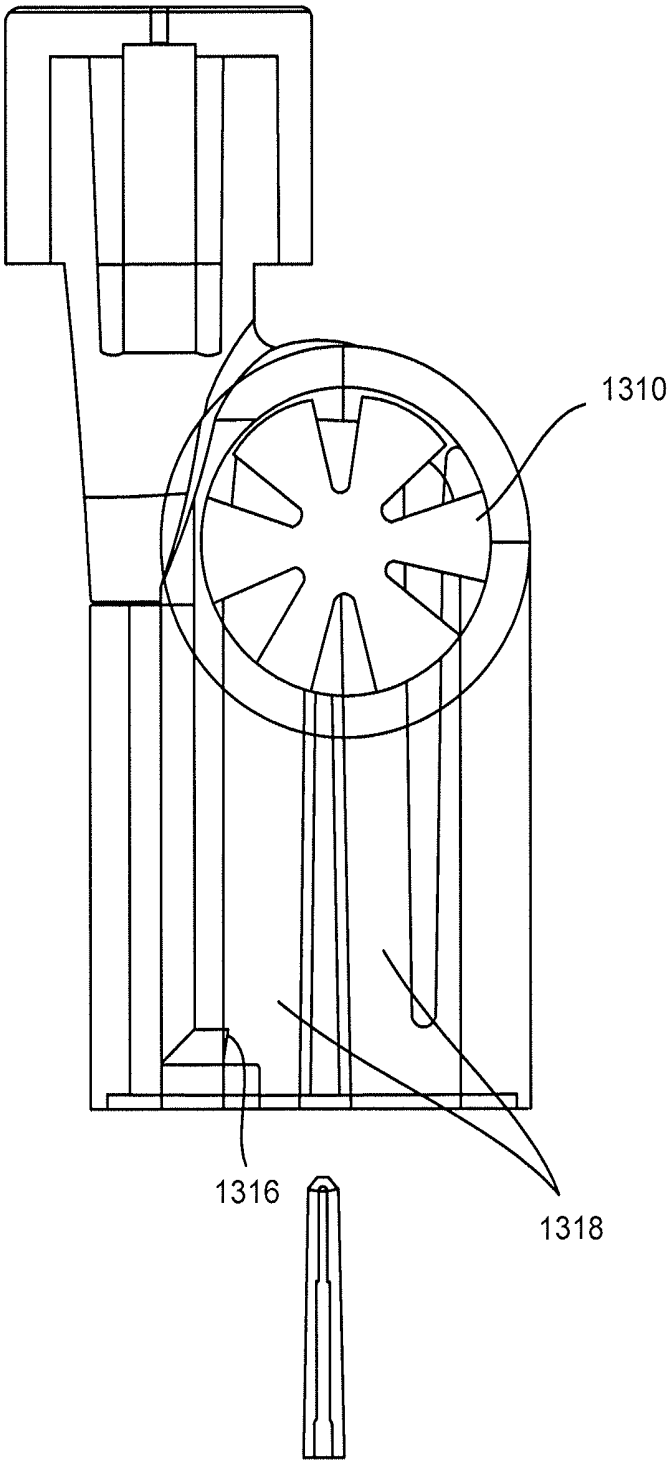


FIG. 13D

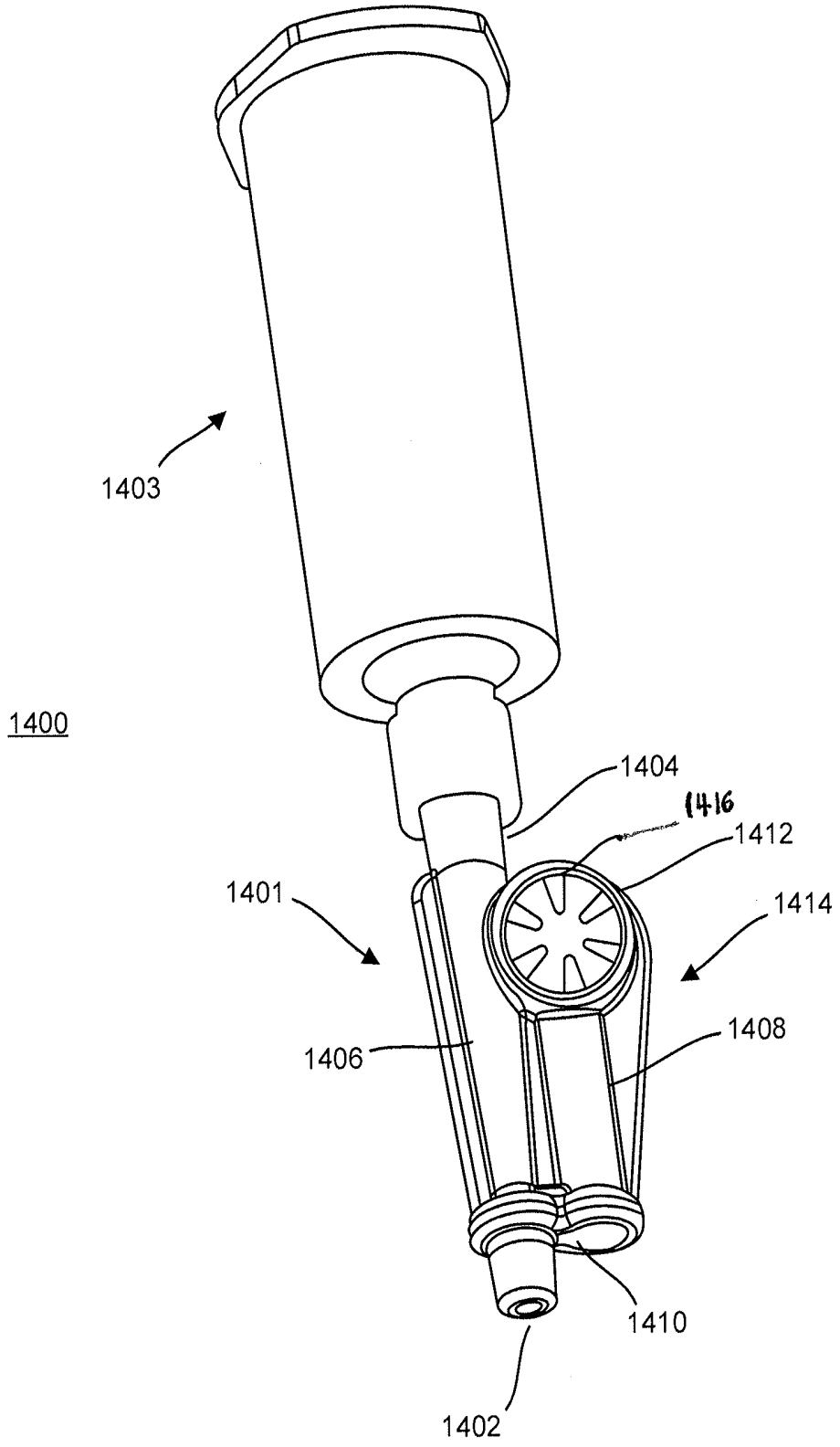


FIG. 14A

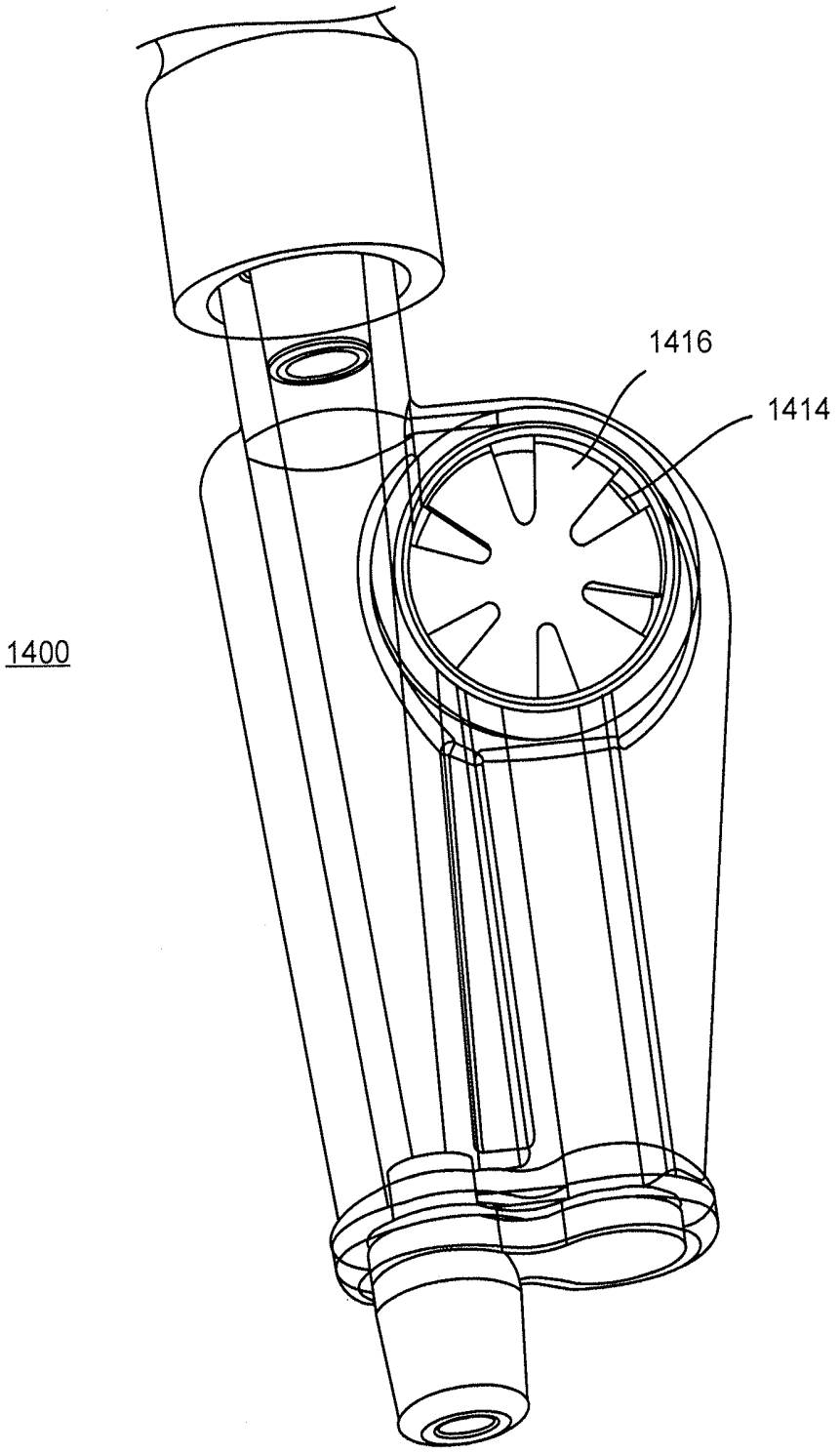
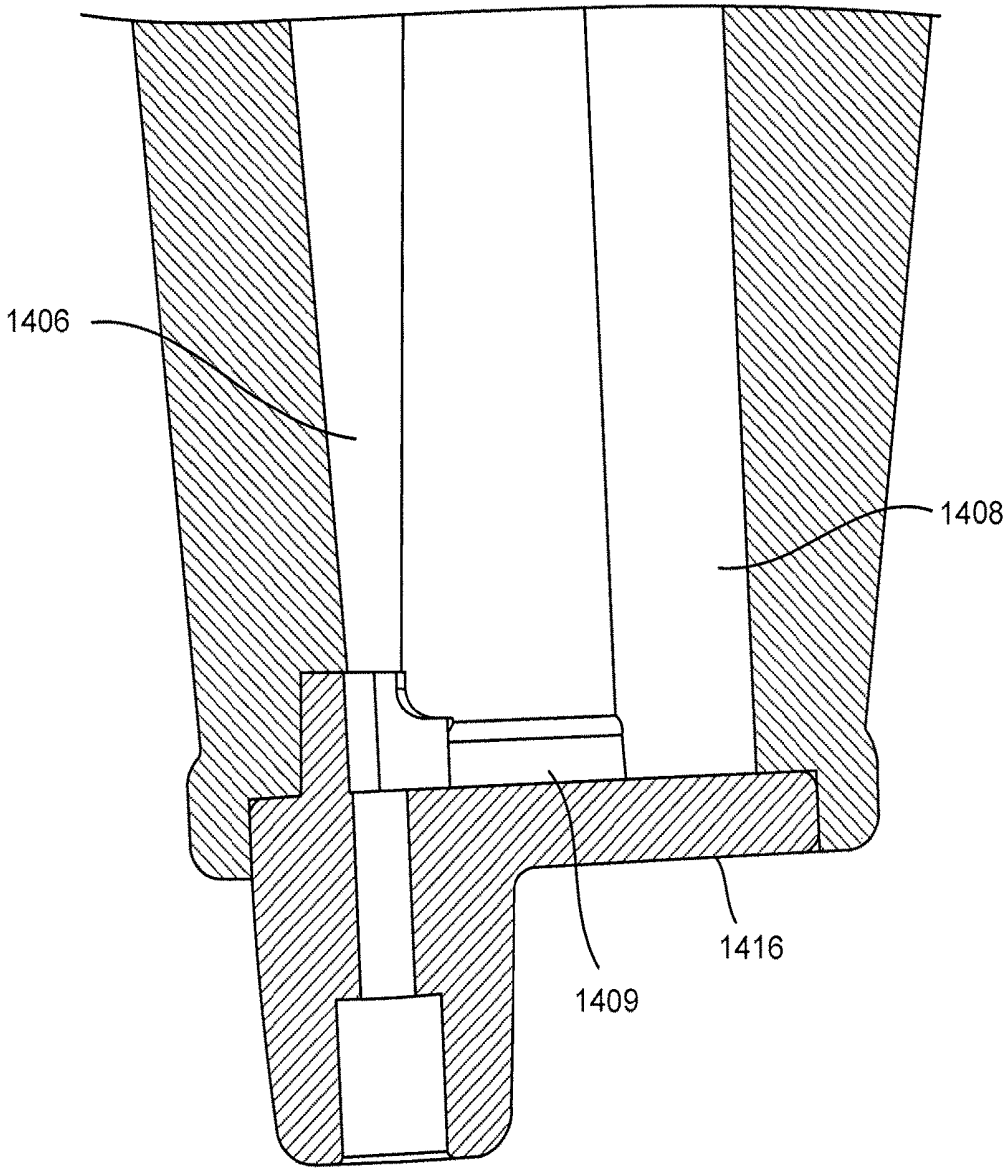


FIG. 14B



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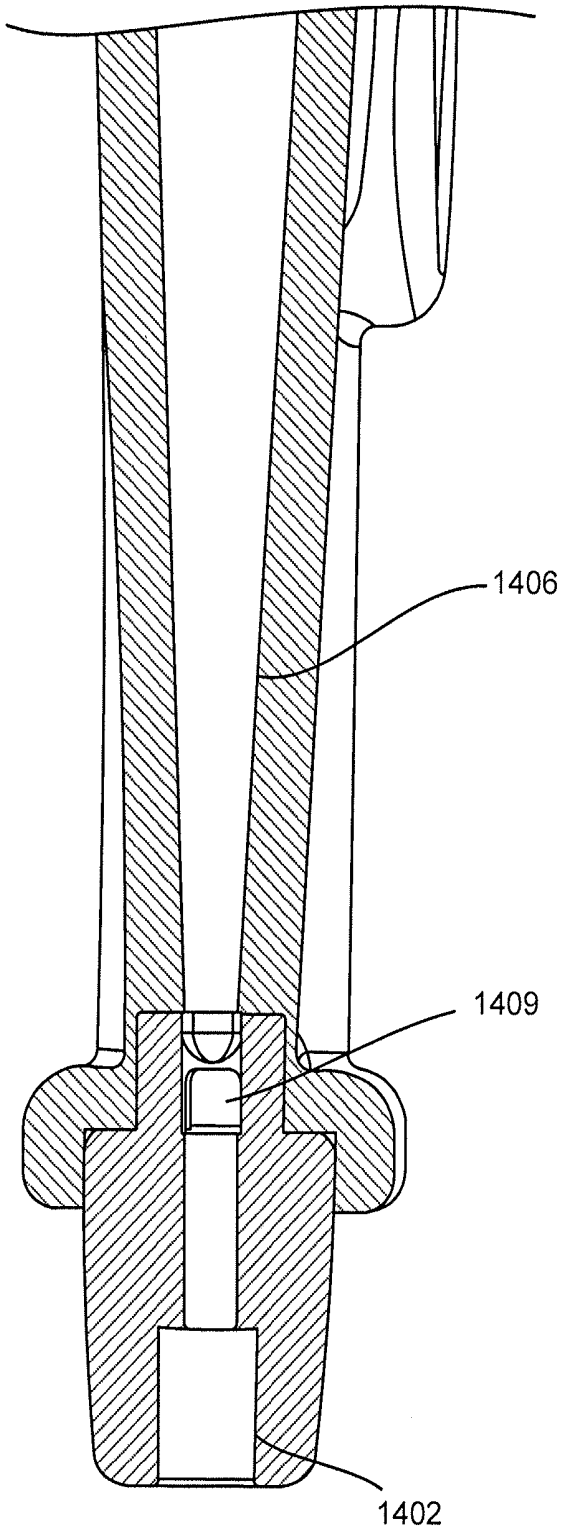

FIG. 14D

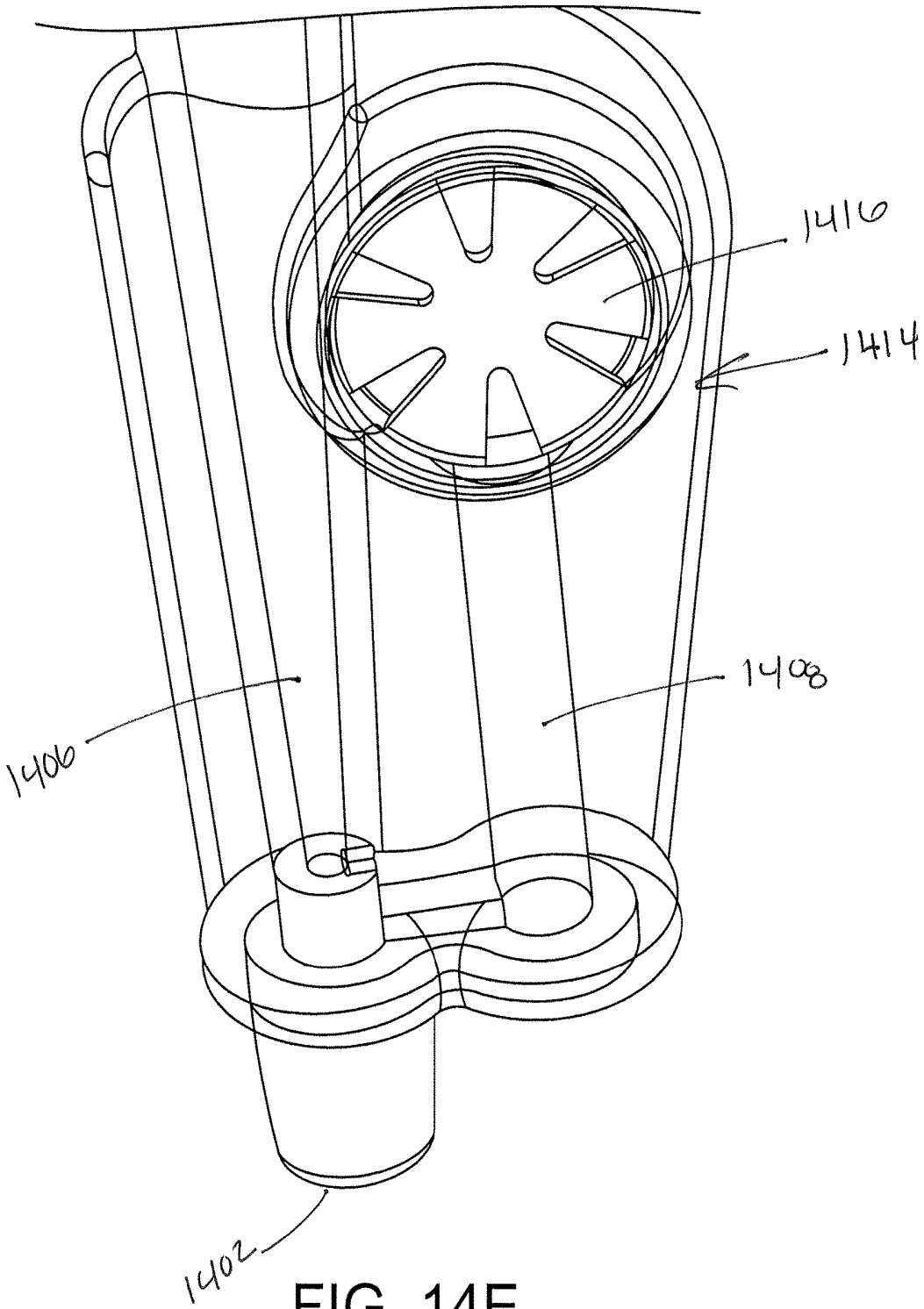

FIG. 14E

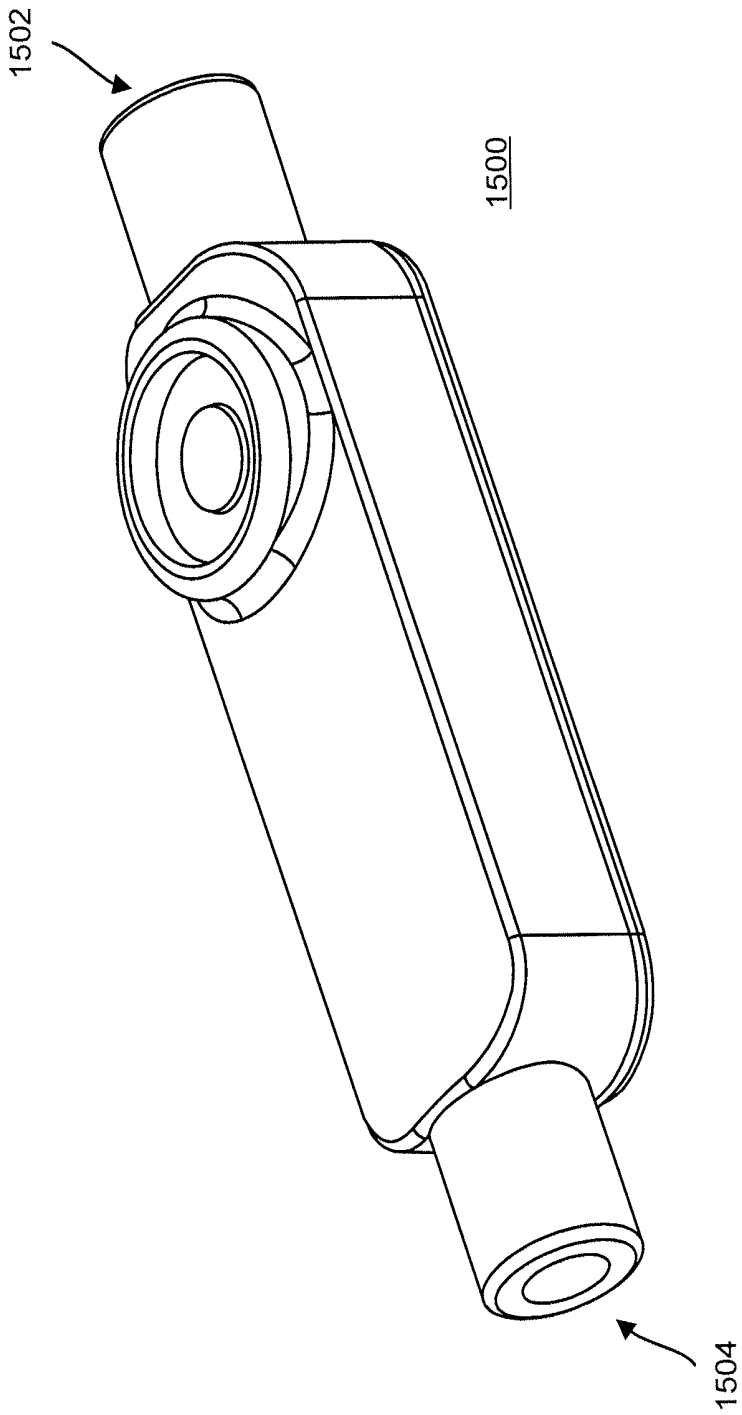

FIG. 15A

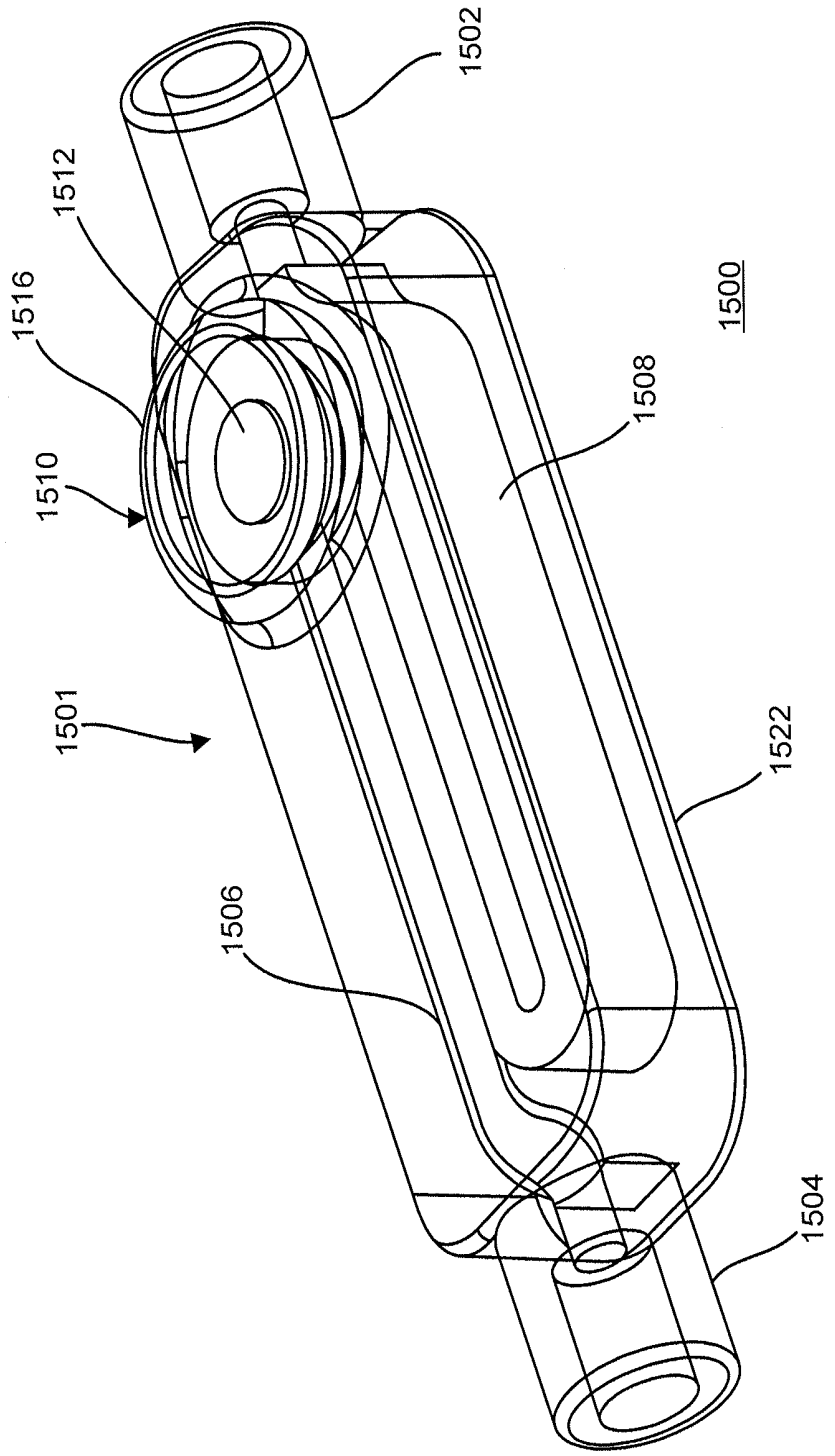

FIG. 15B

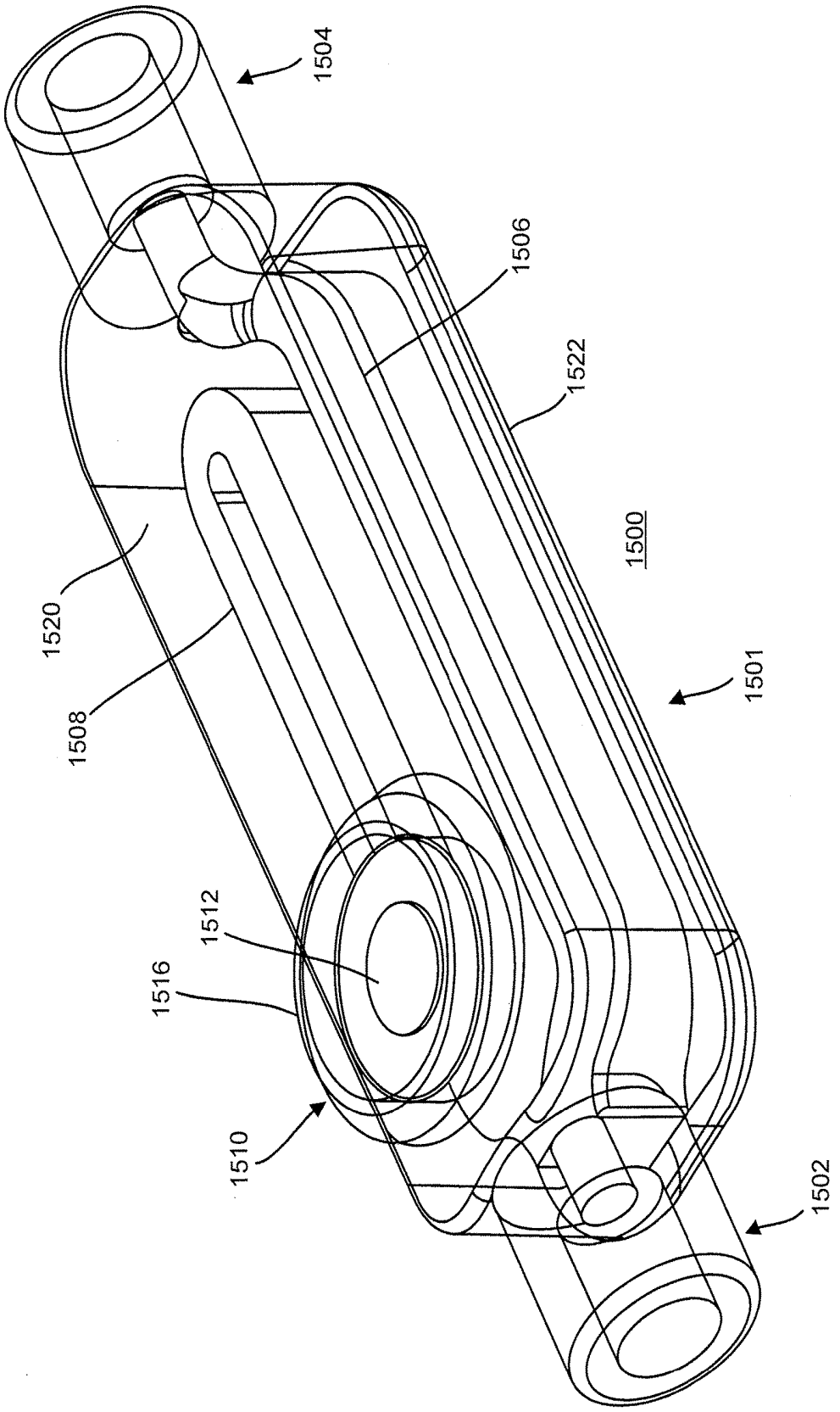

FIG. 15C

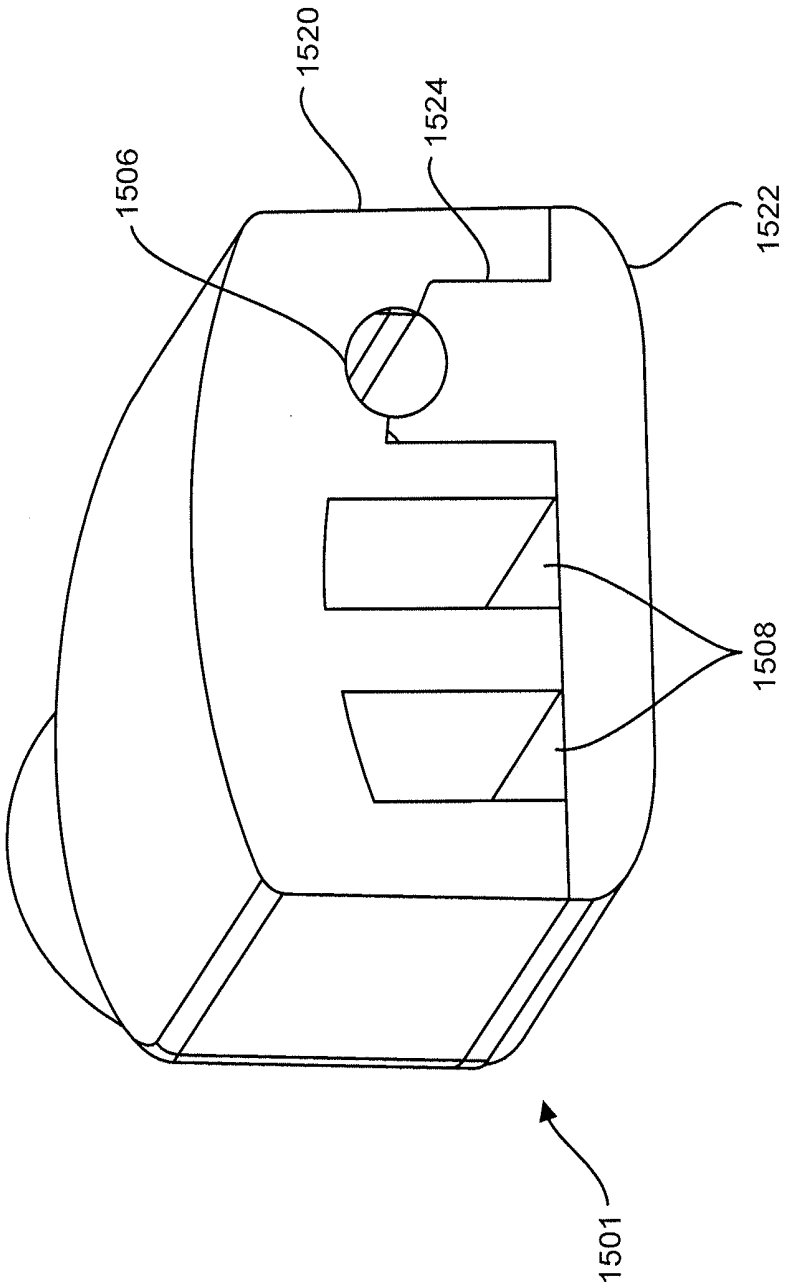

FIG. 15D

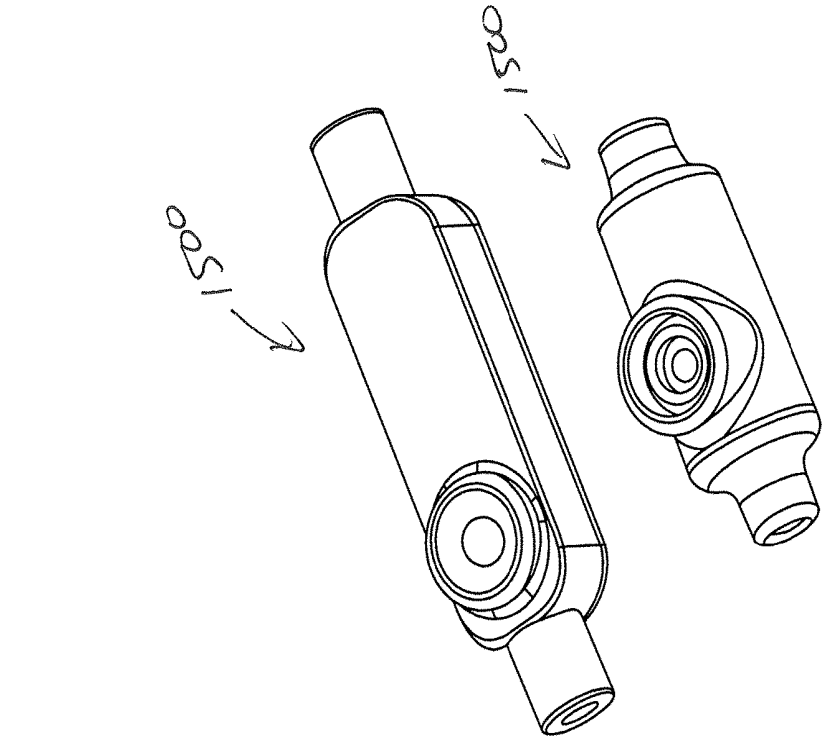

FIG. 15F

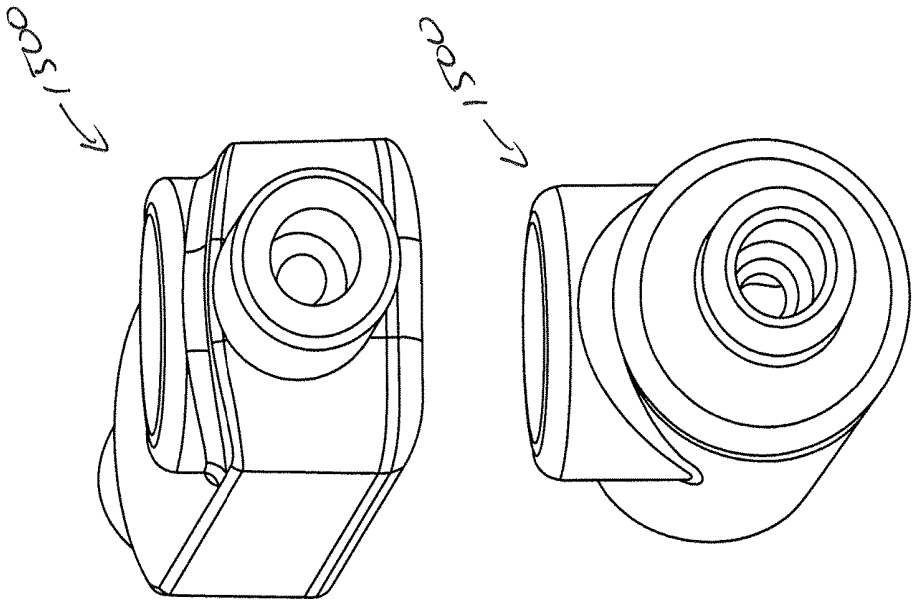

FIG. 15E

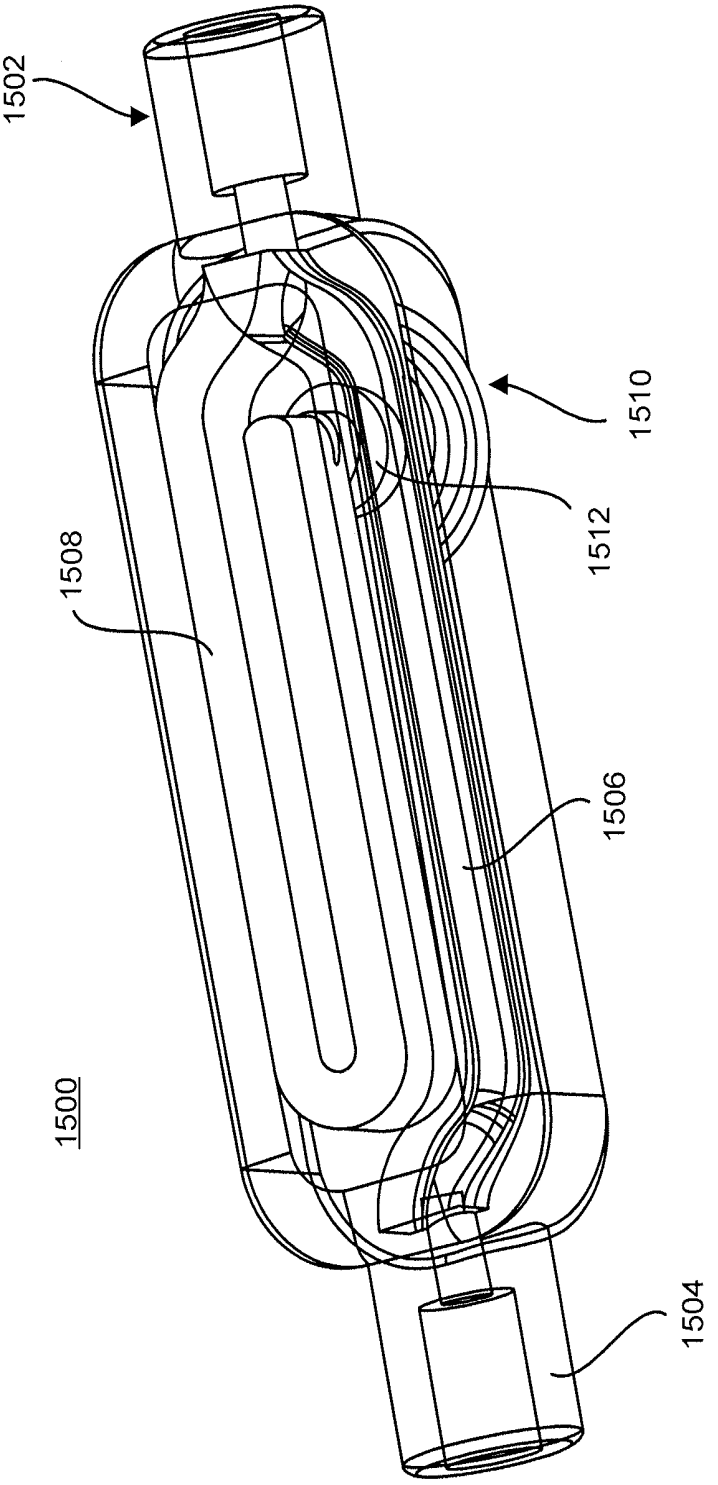

FIG. 15G

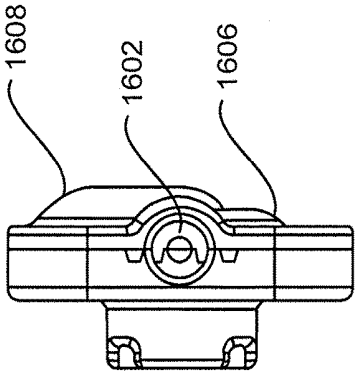

FIG. 16C

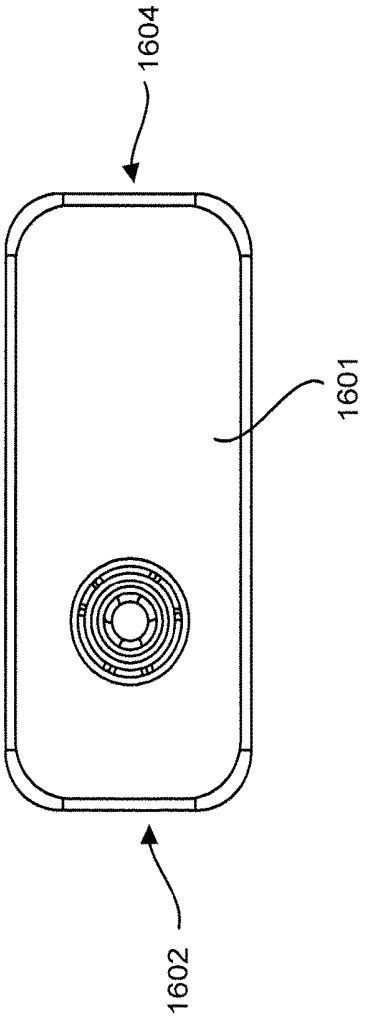

FIG. 16A

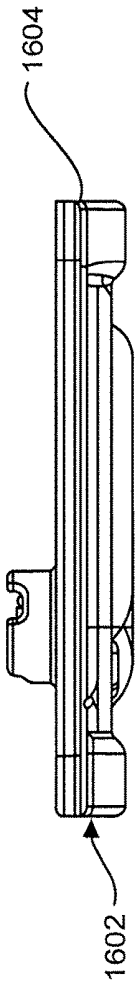

FIG. 16B

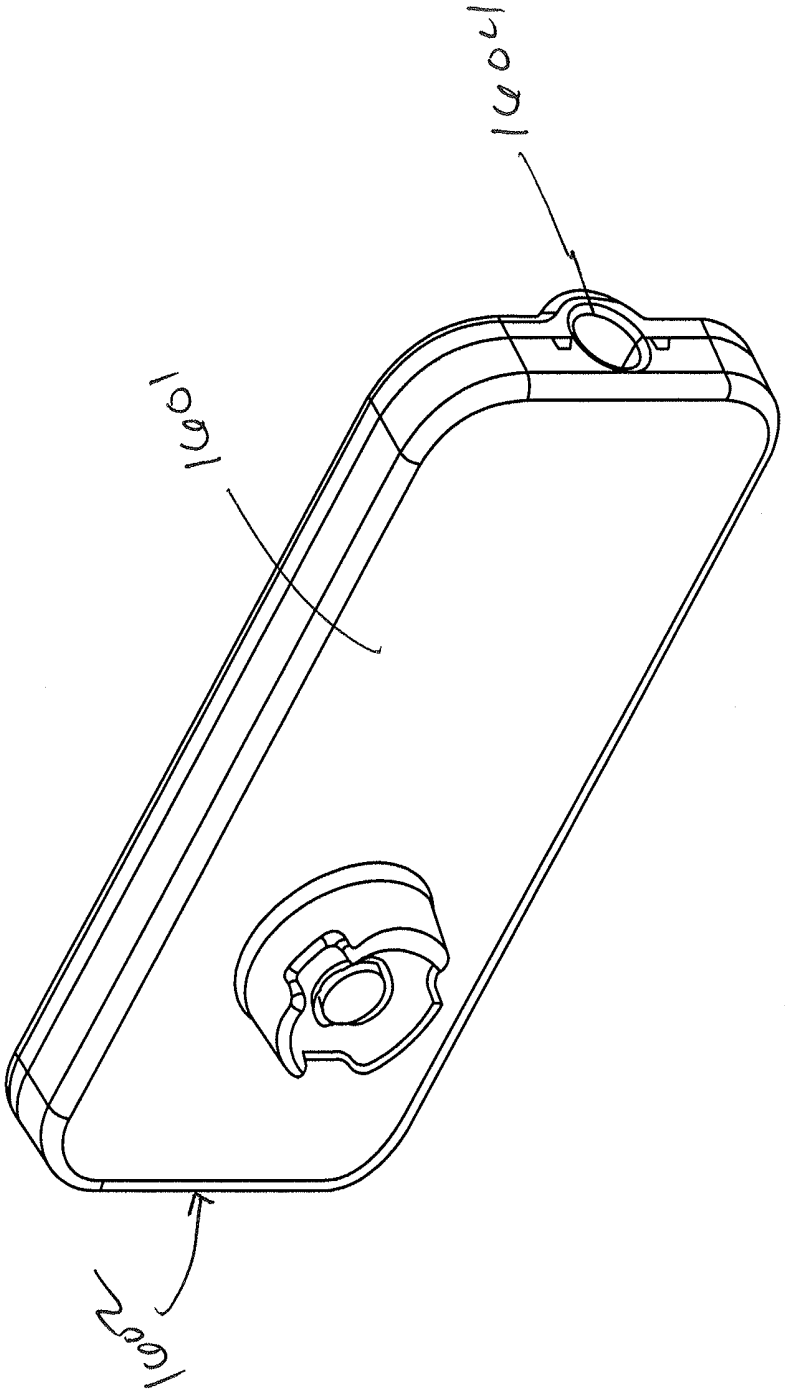

FIG. 16D

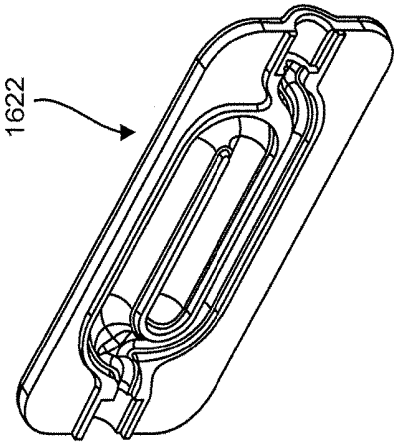

FIG. 17B

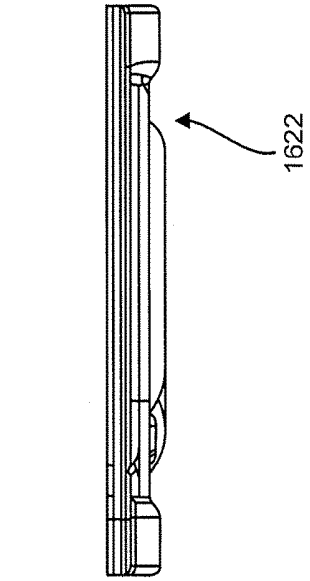

FIG. 17E

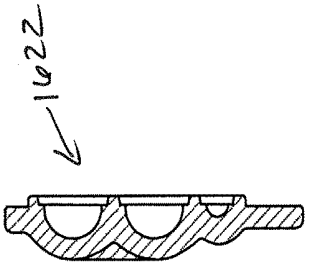

FIG. 17D

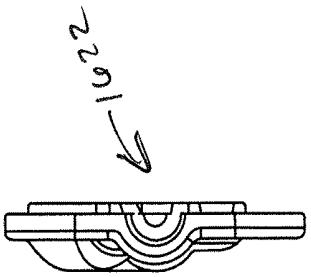

FIG. 17C

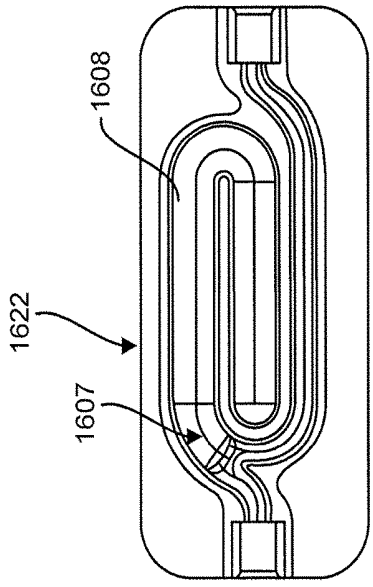

FIG. 17A

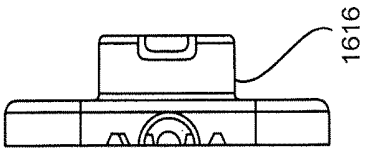

FIG. 18C

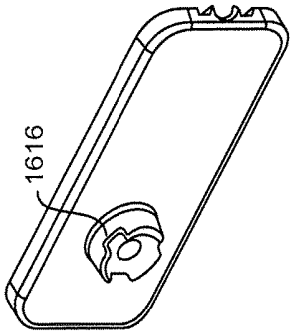

FIG. 18B

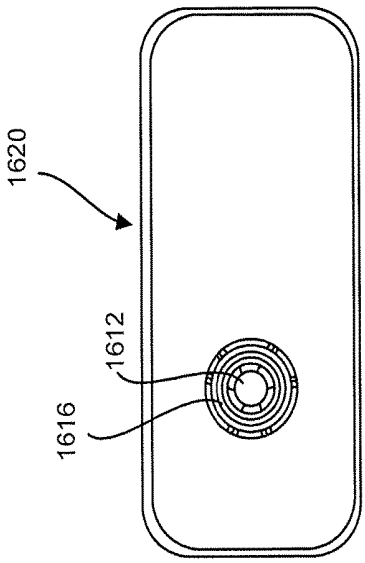

FIG. 18A

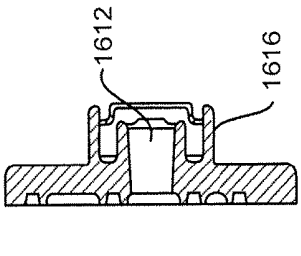

FIG. 18F

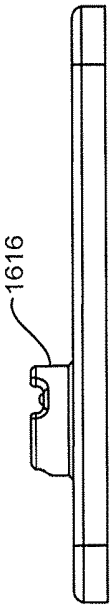

FIG. 18E

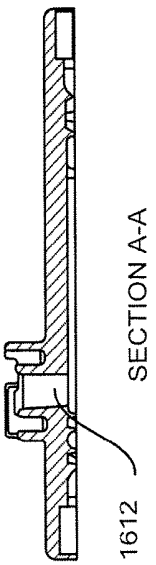

FIG. 18D

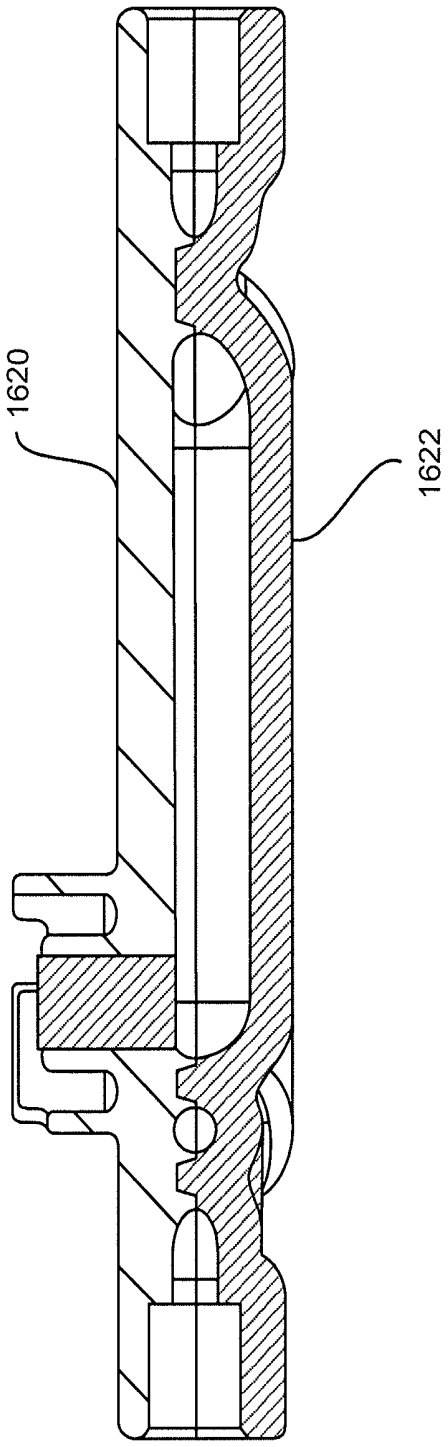

FIG. 19A

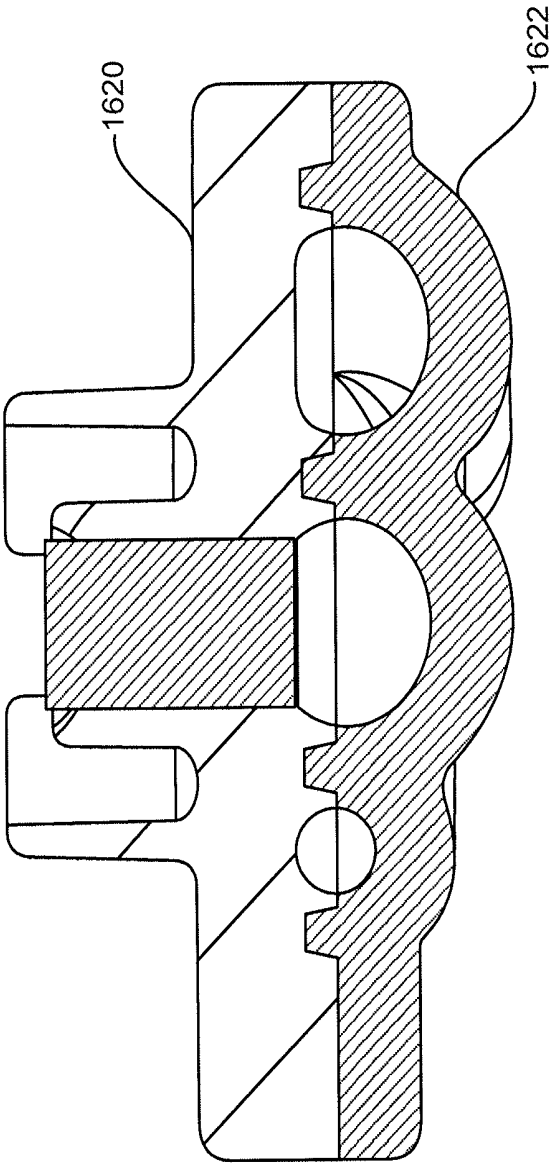

FIG. 19B

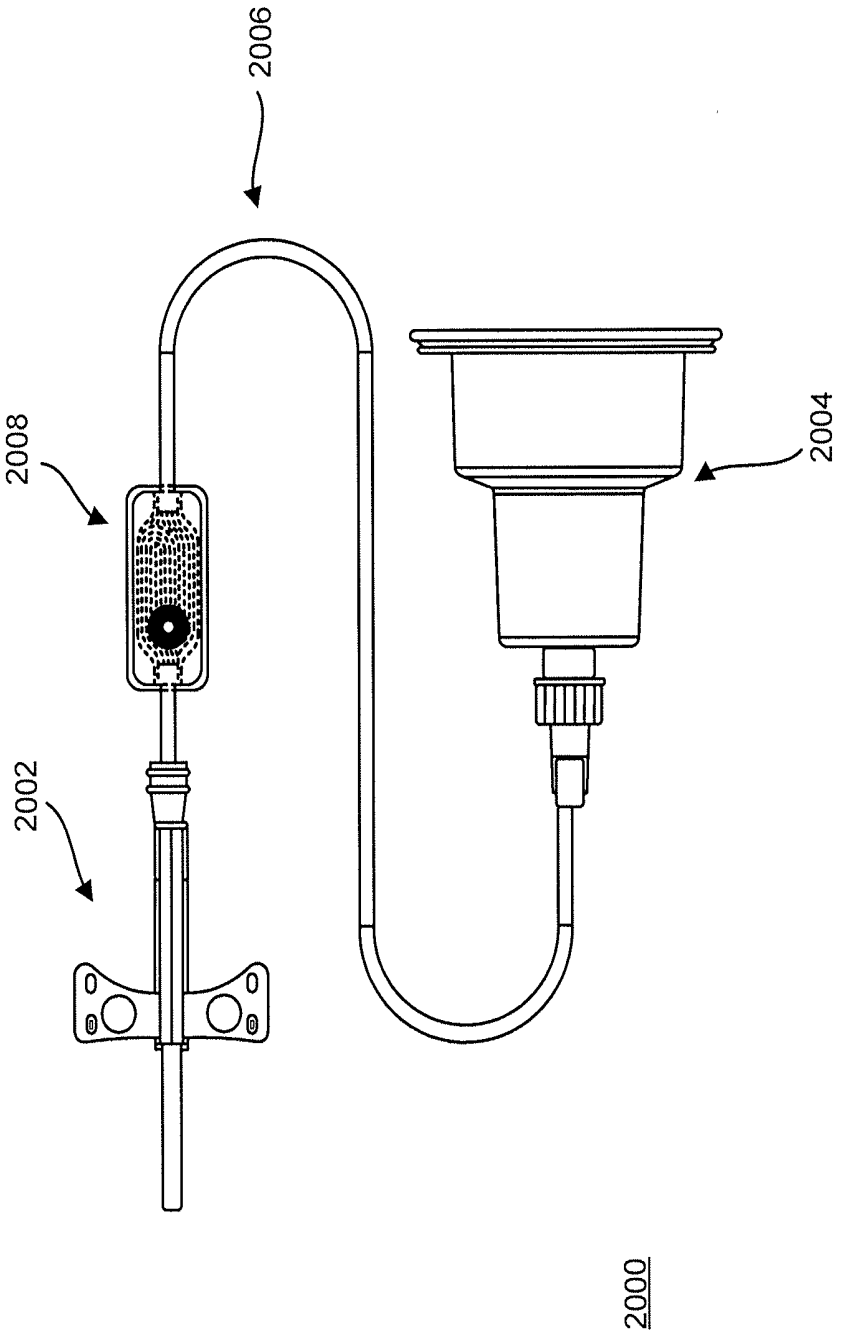

FIG. 20

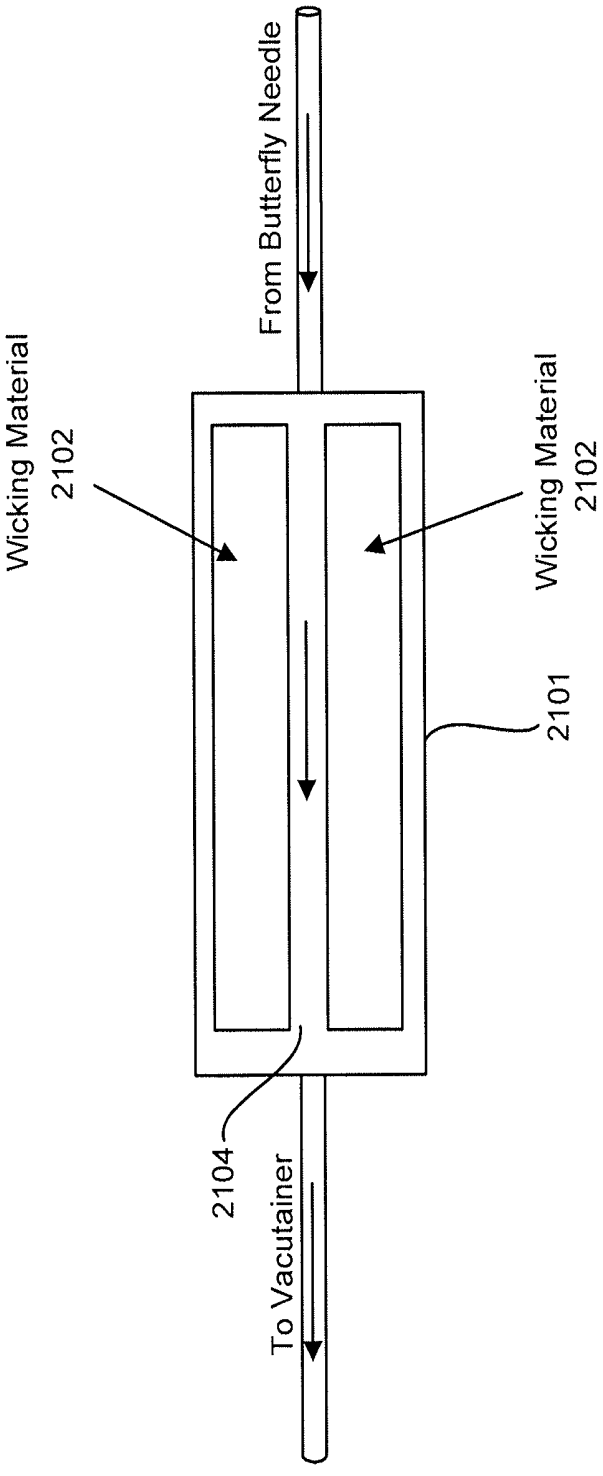
From Butterfly Needle
Wicking Material
2102
Wicking Material
2102
2101
2104
To Vacutainer
2100

FIG. 21

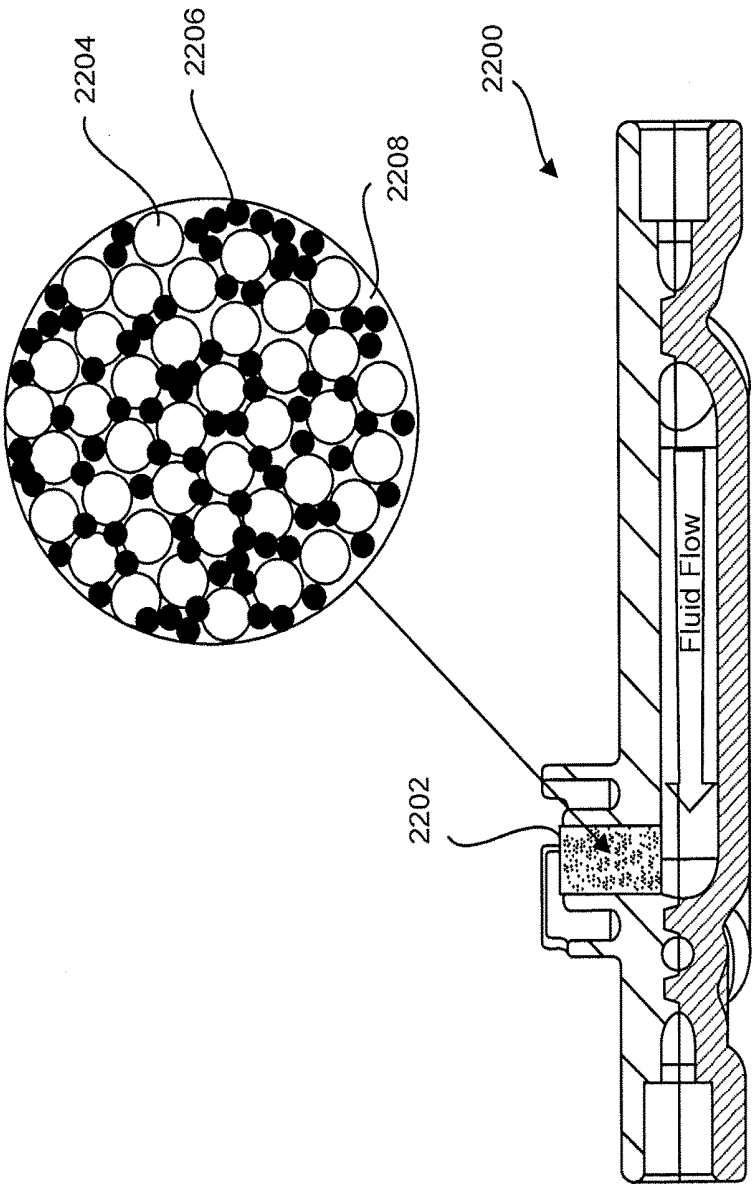

FIG. 22A

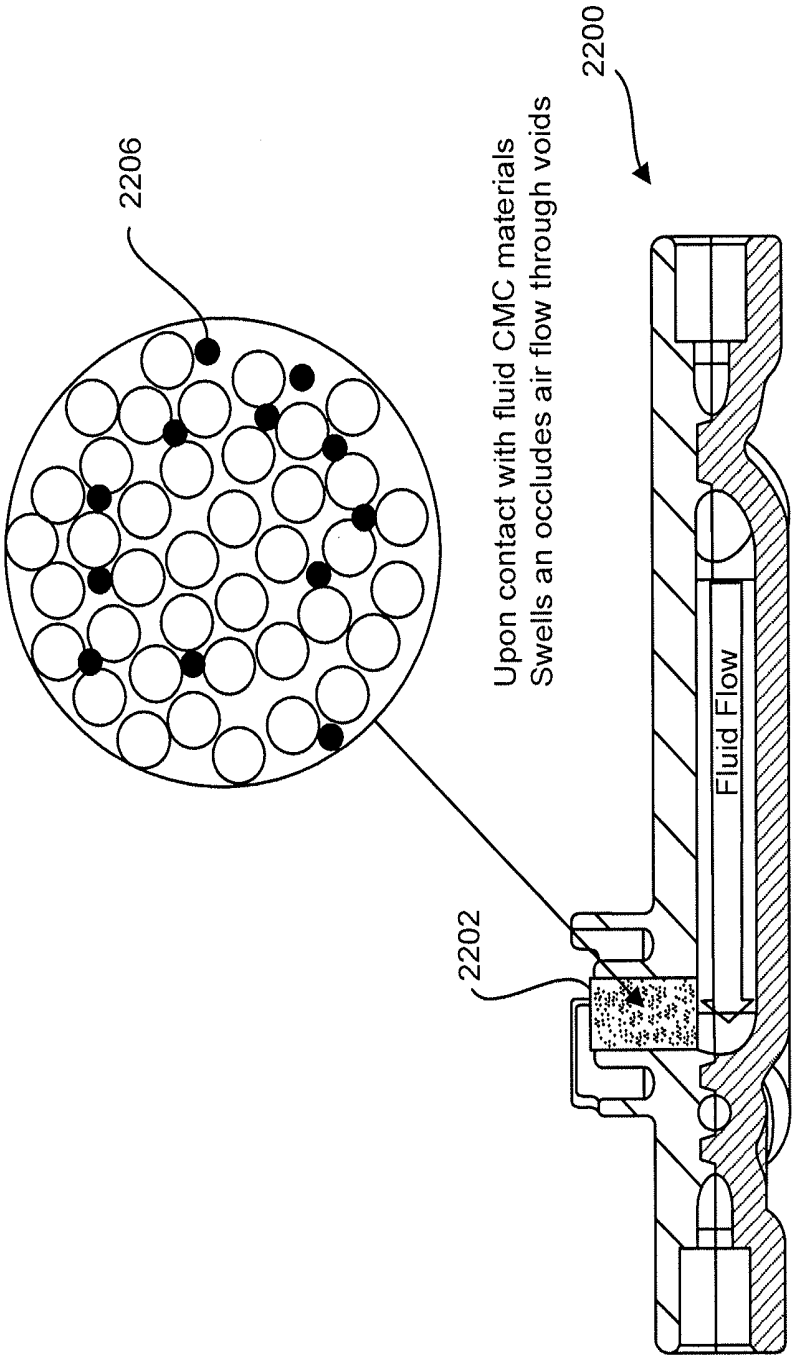
2206
2200
Upon contact with fluid CMC materials
Swells an occludes air flow through voids
Fluid Flow
2202

FIG. 22B

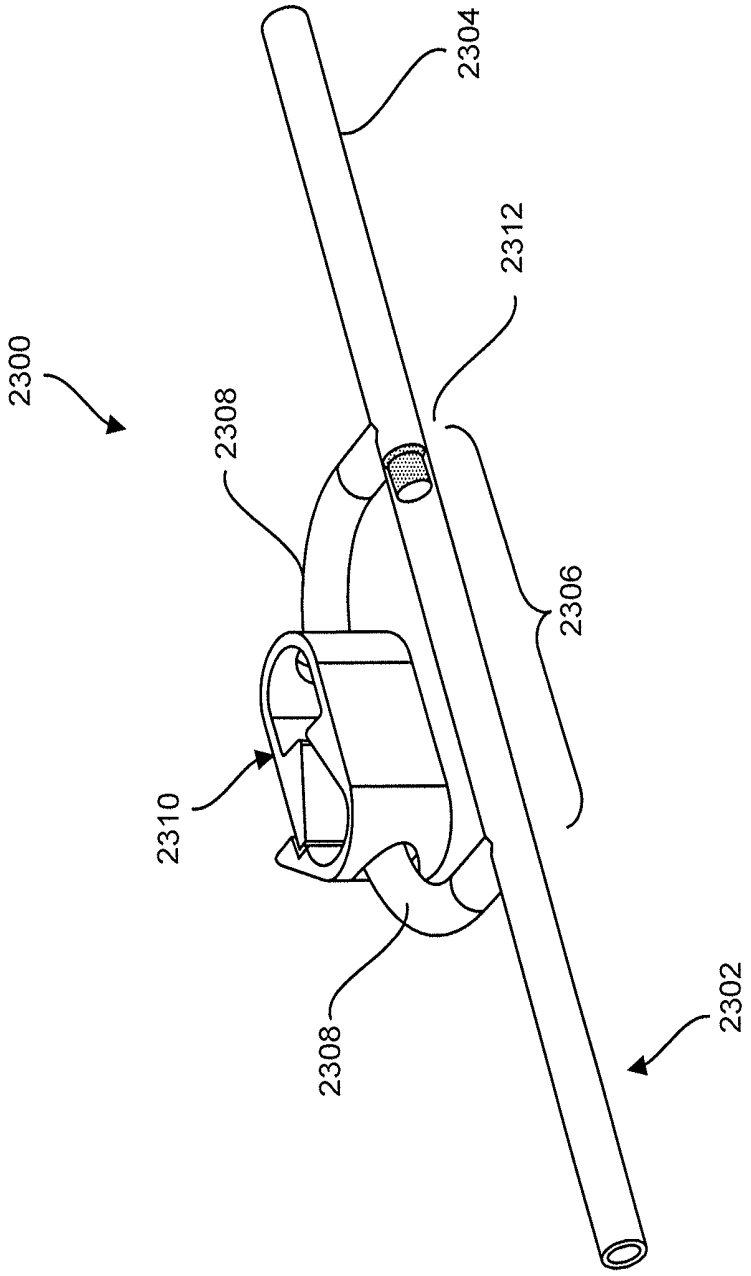

FIG. 23A

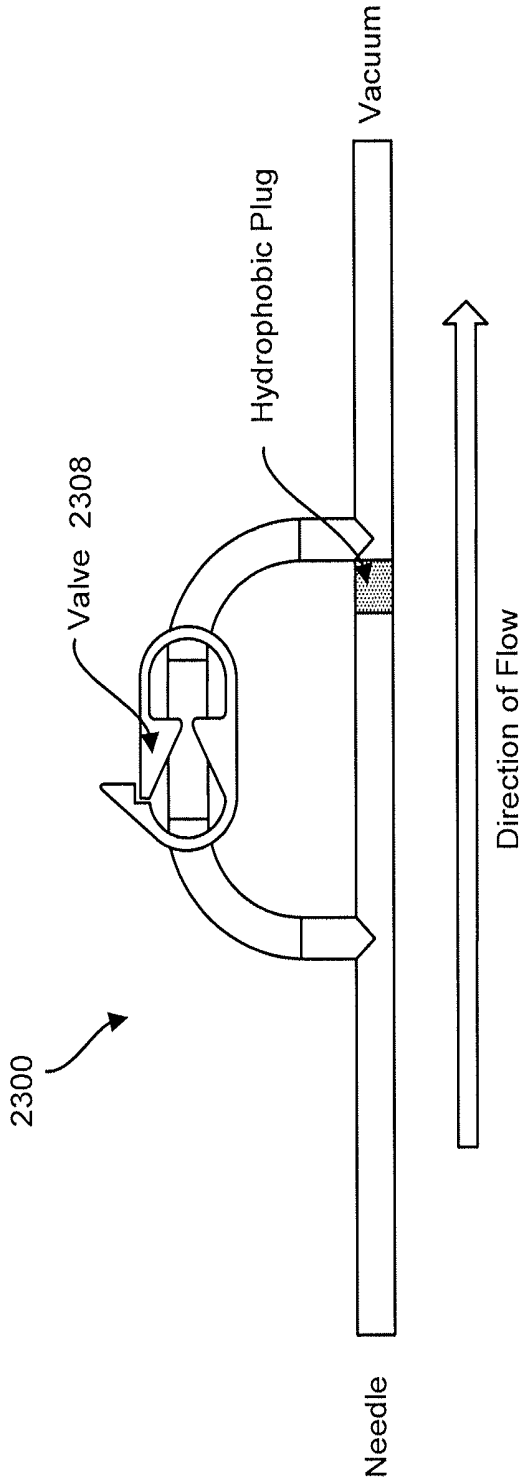
Vacuum
Hydrophobic Plug
Valve 2308
Direction of Flow
2300
Needle

FIG. 23B

BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD

CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims the benefit of U.S. Provisional Application Ser. No. 62/196,797, filed on Jul. 24, 2015 and titled "BLOOD CULTURE IMPROVEMENT SYSTEM AND METHOD"; U.S. Provisional Application Ser. No. 62/238,636, filed on Oct. 7, 2015 and titled "BLOOD SEQUESTRATION SYSTEM FOR NON-CONTAMINATED BLOOD SAMPLING"; and U.S. Provisional Application Ser. No. 62/318,194, filed on Apr. 4, 2016 and titled "BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD," the disclosures of which are incorporated by reference in their entirety.

BACKGROUND

Bacteraemia is the presence of microorganisms in the blood. Sepsis, on the other hand, is bacteraemia in the presence of clinical symptoms and signs such as fever, tachycardia, tachypnea and hypotension. Bacteraemia and sepsis are associated with a high mortality and an increased incidence and duration of hospital stay and associated costs. Many bacteraemias, sepsis, fungaemias and other pathogens actually occur within a hospital or other healthcare settings with catheters and venipunctures being a source of contamination as potential carriers of these pathogens.

Blood cultures are the standard test used to detect microbial pathogens related to bacteraemia and sepsis in a patient's blood. The term blood culture refers to a single venipuncture, either from a peripheral site or central or arterial line, with the blood inoculated into one or more blood culture bottles or containers. One bottle is considered a blood culture where two or more are considered a set. Multiple sets may be obtained from multiple venipunctures and are associated with different sites on the patient.

These methods allow for microbial identification and susceptibility testing to be performed, which is a critical component to managing sepsis, however the lack of rapid results and decreased sensitivity for fastidious pathogens has led to the development of improved systems and adjunctive molecular or proteomic testing.

Collection of blood samples for conducting blood cultures is a critical component of modern patient care and can either positively affect the patient outcome by providing an accurate diagnosis, or can adversely affect the outcome by prolonging unnecessary antimicrobial therapy, the length of hospital stays, and increasing costs.

One outcome of collection of blood cultures is contamination. Blood culture contamination can lead to a false positive culture result and/or significant increase in healthcare related costs. Sources of blood culture contamination include improper skin antisepsis, improper collection tube disinfection, and contamination of the initial blood draw which may then skew results.

Blood culture collection kits generally consist of a "butterfly" set, infusion set, or other type of venipuncture device as offered by companies like BD, Smiths, B. Braun and others, and aerobic and anaerobic blood culture bottles. Various different bottles are also available depending on the test requirements. These bottles are specifically designed to optimize recovery of both aerobic and anaerobic organisms.

In conventional kits, a bottle used is known generally as a "Vacutainer," which is a blood collection tube formed of a sterile glass or plastic tube with a closure that is evacuated to create a vacuum inside the tube to facilitate the draw of a predetermined volume of liquid such as blood.

False positive blood cultures are typically a result of poor sampling techniques. They cause the use of antibiotics when not needed, increasing hospital costs and patient anxiety. Blood cultures are drawn from a needlestick into the skin, and then a Vacutainer is attached to capture a sample of blood. Contamination may occur from improper or incomplete disinfection of the skin area in and around the puncture site. It may also occur from the coring of the skin by the needle during insertion, with the cored skin cells and any associated contamination being pulled into the sample.

Blood flow through a hypodermic needle is laminar, and as such, a velocity gradient can be developed over the flow tube as a pressure drop is applied to the hypodermic needle. Either forceful aspiration of blood, or using a very small hypodermic needle, can cause lysis and a release of potassium from the red blood cells, thereby rendering the blood samples abnormal.

In other instances, some patients have delicate veins that can collapse under a pressure drop or vacuum, particularly as applied by a syringe's plunger that is drawn too quickly for the patient's condition. Since such condition is impossible to know beforehand, such vein collapses are a risk and very difficult to control.

Various strategies have been implemented to decrease blood culture contamination rates, e.g. training staff with regard to aseptic collection technique, feedback with regard to contamination rates and implementation of blood culture collection kits. Although skin antisepsis can reduce the burden of contamination, 20% or more of skin organisms are located deep within the dermis and are unaffected by antisepsis. Changing needles before bottle inoculation is not advisable as it increases the risk to acquire needle stick injuries without decreasing contamination rates.

Some conventional systems and techniques for reducing blood culture contamination include discarding the initial aliquot of blood taken from central venous catheters, venipunctures, and other vascular access systems. However, these systems require the user to mechanically manipulate an intravascular device, or require a complex series of steps that are difficult to ensure being followed.

SUMMARY

This document presents systems and methods for reducing blood culture contamination, lysing of cells, and vein collapse. In some implementations, a system and method can eliminate user variability in disinfection, and also eliminate the risk of skin cells getting into the blood culture sample. The systems and methods disclosed herein do not require a change in existing clinical processes, other than to potentially indicate when a vacutainer or other blood collection device (i.e., syringe) should be attached for drawing contaminant-free blood samples.

In some implementations of the systems and methods disclosed herein the withdrawal of blood is accomplished passively by use of the patient's own blood pressure, thereby reducing the risk of vein collapse and eliminating any additional user steps over current practice. The systems and methods can be applied to accommodate short-path direct stick or butterfly venipuncture systems. They can also be used with samples drawn through a catheter.

In one aspect, a blood sequestration device is presented. The blood sequestration device includes an inlet port and an outlet port. The blood sequestration device further includes a sequestration chamber connected with the inlet port, the sequestration chamber having a vent comprising an air permeable blood barrier. The blood sequestration device can further include a sampling channel having a proximal end connected with the inlet port and a distal end connected with the outlet port.

In another aspect, a blood sequestration device connected with a blood sampling pathway is described. The blood sampling pathway can have a patient needle and a sample collection device. The blood sequestration device includes an inlet port connected with the patient needle, and a sequestration chamber connected with the inlet port, the sequestration chamber having a vent comprising an air permeable blood barrier. The blood sequestration device further includes a sampling channel having a proximal end connected with the inlet port, and an outlet port connected with a distal end of the sampling channel and with the sample collection device.

In yet another aspect, a blood sequestration device connected with a blood sampling system is described. The blood sampling system includes a patient needle for accessing a blood sample from a patient, and a sample needle that is sealed and adapted for receiving an evacuated blood collection tube. The blood sequestration device includes an inlet port connected with the patient needle to receive the blood sample from the patient. The blood sequestration device further includes a sequestration chamber connected with the inlet port and having a vent comprising an air permeable blood barrier, the sequestration chamber for receiving and sequestering a first portion of the blood sample prior to the sample needle being unsealed by the evacuated blood collection tube. The blood sequestration device further includes a sampling channel having a proximal end connected with the inlet port, the sampling channel for conveying a subsequent portion of the blood sample once the sample needle is unsealed by the evacuated blood collection tube. The blood sequestration device further includes an outlet port connected with a distal end of the sampling channel for conveying the subsequent portion of the blood sample to the sample needle.

In yet another aspect, a blood sample optimization system is disclosed and described. The blood sample optimization system includes a blood sampling system for accessing and acquiring one or more samples of a patient's blood, and a blood sequestration device for receiving and sequestering a first portion of the one or more samples of the patient's blood which might be contaminated by a venipuncture process and which could result in a false positive identification of a pathogen in the patient's blood.

The blood sampling system includes a patient needle configured for a venipuncture of a patient to access a sample of blood of a patient, a blood sampling pathway connected with the patient needle for conveying the sample of blood, and a sample needle configured for receiving an evacuated blood collection container to collect and contain a subsequent portion of the sample of blood.

The blood sequestration device is connected along the blood sampling pathway between the patient needle and the sample needle, and includes an inlet port for receiving the sample of blood. The blood sequestration device further includes a sequestration chamber connected with the inlet port for receiving a first amount of the sample of blood, the sequestration chamber having a vent comprising an air permeable blood barrier for sequestering at least a first portion of the first amount of the sample of blood. The blood sequestration device may further include a sampling channel having a proximal end connected with the inlet port, the sampling channel conveying a subsequent amount of the sample of blood to the evacuated blood collection container upon the sequestration chamber sequestering at least the first portion of the first amount of the sample of blood. The blood sequestration device further includes an outlet port connected with a distal end of the sampling channel, the outlet port for outputting the subsequent amount of the sample of blood.

The details of one or more embodiments are set forth in the accompanying drawings and the description below. Other features and advantages will be apparent from the description and drawings, and from the claims.

BRIEF DESCRIPTION OF THE DRAWINGS

These and other aspects will now be described in detail with reference to the following drawings.

FIG. **1** illustrates a blood sample optimization system.

FIG. **2** illustrates a blood sample optimization system in accordance with an alternative implementation.

FIG. **3** illustrates a blood sample optimization system in accordance with another alternative implementation.

FIG. **4** illustrates a blood sample optimization system in accordance with another alternative implementation.

FIG. **5** illustrates a blood sample optimization system in accordance with another alternative implementation.

FIG. **6** illustrates a blood sample optimization system in accordance with an alternative implementation.

FIG. **7** is a flowchart of a method for optimizing a quality of a blood culture.

FIGS. **8**A-**8**E illustrate a blood sequestration system for non-contaminated blood sampling, in accordance with some implementations.

FIG. **9** illustrates a pathway splitter for use in a blood sequestrations system.

FIGS. **10**A-**10**D illustrate a blood sequestration system for non-contaminated blood sampling, in accordance with alternative implementations.

FIGS. **11**A-**11**E illustrate a blood sequestration system for non-contaminated blood sampling, in accordance with other alternative implementations.

FIGS. **12**A-**12**D illustrate a blood sample optimization system including a blood sequestration device in accordance with yet other alternative implementations.

FIGS. **13**A-**13**D illustrate a blood sample optimization system **1300** in accordance with yet another alternative implementations.

FIGS. **14**A-**14**E illustrate yet another implementation of a blood sampling system to sequester contaminates of an initial aliquot or sample to reduce false positives in blood cultures or tests performed on a patient's blood sample.

FIGS. **15**A-**15**G illustrate a blood sequestration device and method of using the same, in accordance with yet another implementation.

FIGS. **16**A-**16**D illustrate a blood sequestration device in accordance with yet another implementation.

FIGS. **17**A-**17**E illustrate a bottom member of a housing for a blood sequestration device.

FIGS. **18**A-**18**F illustrate a top member of a housing for a blood sequestration device.

FIGS. **19**A and **19**B illustrate a blood sequestration device having a top member mated with a bottom member.

FIG. **20** shows a blood sample optimization system including a blood sequestration device.

FIG. **21** illustrates a non-vented blood sequestration device using a wicking material chamber.

FIGS. **22**A and **22**B illustrate a material makeup of a filter for sequestering blood in a sequestration chamber of a blood sequestration device.

FIGS. **23**A and **23**B illustrate another implementation of a blood sequestration device that uses a vacuum force from a blood collection device.

Like reference symbols in the various drawings indicate like elements.

DETAILED DESCRIPTION

This document describes blood sample optimization systems and methods for reducing or eliminating contaminates in collected blood samples, which in turn reduces or eliminates false positive readings in blood cultures or other testing of collected blood samples. In some implementations, a blood sample optimization system includes a patient needle for vascular access to a patient's bloodstream, a sample needle for providing a blood sample to a blood collection container, such as an evacuated blood collection container or tube like a Vacutainer™ or the like, or other sampling device, and a blood sequestration device located between the patient needle and the sample needle. The blood sequestration device includes a sequestration chamber for sequestering an initial, potentially contaminated aliquot of blood, and may further include a sampling channel that bypasses the sequestration chamber to convey likely uncontaminated blood between the patient needle and the sample needle after the initial aliquot of blood is sequestered in the sequestration chamber.

FIG. **1** illustrates a blood sample optimization system in accordance with some implementations. The system includes a patient needle **1** to puncture the skin of a patient to access the patient's vein and blood therein. The system further includes a sample needle (i.e., a resealably closed needle for use with Vacutainers™ or the like) **5**, which may be contained within and initially sealed by a resealable boot **10**, a Luer activated valve, or another collection interface or device. The resealable boot **10** can be pushed aside or around the sample needle **5** by application of a Vacutainer™ bottle (not shown) for drawing the patient's blood. The system can further include a low volume chamber **30** that leads to the sample needle **5**, but also includes an orifice or one or more channels **45** that lead to a sequestration chamber **55** formed by a housing **50**.

The sequestration chamber **55** is a chamber, channel, pathway, lock, or other structure for receiving and holding a first aliquot of the patient's blood, which may be in a predetermined or measured amount, depending on a volume of the sequestration chamber **55**. The first draw of blood typically contains or is more susceptible to containing organisms that cause bacteraemia and sepsis or other pathogens than subsequent blood draws. The sequestration chamber **55** can be a vessel encased in a solid housing, formed in or defined by the housing itself, or can be implemented as tubing or a lumen. The sequestration chamber **55**, regardless how formed and implemented, may have a predetermined volume. In some implementations, the predetermined volume may be based on a volume of the patient needle, i.e. ranging from less than the volume of the patient needle to any volume up to or greater than 20 times or more of the volume of the patient needle. The predetermined volume of the sequestration chamber **55** may also be established to economize or minimize an amount of blood to be sequestered and disposed of.

The sequestration chamber **55** can be formed, contained or housed in a chamber housing **50**, and can be made of plastic, rubber, steel, aluminum or other suitable material. For example, the sequestration chamber **55** could be formed of flexible tubing or other elastomeric materials. The sequestration chamber **55** further includes an air permeable blood barrier **20** that allows air to exit the sequestration chamber **55**. As used herein the term "air permeable blood barrier" means an air permeable but substantially blood impermeable substance, material, or structure. Examples may include hydrophobic membranes and coatings, a hydrophilic membrane or coating combined with a hydrophobic membrane or coating, mesh, a filter, a mechanical valve, antimicrobial material, or any other means of allowing air to be displaced from the sequestration chamber **55** as it is filled with blood. In various exemplary embodiments, an air permeable blood barrier may be formed by one or more materials that allow air to pass through until contacted by a liquid, such material then becomes completely or partially sealed to prevent or inhibit the passage of air and/or liquid. In other words, prior to contact with liquid, the material forms a barrier that is air permeable. After contact with a liquid, the material substantially or completely prevents the further passage of air and/or liquid.

The orifice or channel **45** can be any desired length, cross-sectional shape or size, and/or can be formed to depart from the low volume chamber **30** at any desired angle or orientation. The orifice or channel **45** may also include a one-way flap or valve **60** that maintains an initial aliquot of blood sample within the sequestration chamber **55**. In some specific implementations, the orifice or channel **45** can include a "duck bill" or flapper valve **60**, or the like, for one-way flow of blood from low volume chamber **30** to the sequestration chamber **55**. The air permeable blood barrier **20** can also be constructed of a material that allows air to exit but then seals upon contact with blood, thereby not allowing external air to enter sequestration chamber **55**. This sealing would eliminate the need for a valve.

Valve **60** can be any type of valve or closing mechanism. Chamber **30** is designed to hold virtually no residual blood, and can be designed to be adapted to hold or allow passthrough of a particular volume or rate of blood into sequestration chamber **55**. Likewise, sequestration chamber **55** may also include any type of coating, such as an antimicrobial coating, or a coating that aids identification and/or diagnosis of components of the first, sequestered blood draw.

Housing **50** and **40** can be formed of any suitable material, including plastic, such as acrylonitrile butadiene styrene (ABS) or other thermoplastic or polymeric material, rubber, steel, or aluminum. The air permeable blood barrier **20** can include a color-providing substance, or other signaling mechanism, that is activated upon contact with blood from the initial blood draw, or when air displacement is stopped, or any combination of events with blood in the sequestration chamber **55**. The air permeable barrier may also include an outer layer such as a hydrophobic membrane or cover that inhibits or prevents the inadvertent or premature sealing of the filter by an external fluid source, splash etc. Sequestration chamber **55** can also be translucent or clear to enable a user to visually confirm the chamber is filled.

FIG. **2** illustrates a blood sample optimization system in accordance with some alternative implementations. In the implementation shown in FIG. **2**, a sequestration chamber **55**, or waste chamber, surrounds the patient needle **1**, with an open-ended cuff or housing connected with the waste chamber and encircling the sample needle housing base and

housing. The patient needle **1** and sample needle **5** are connected together by a boot **56**, which forms a continuous blood draw channel therethrough. The boot **56** includes a single orifice or channel leading from the blood draw channel into sequestration chamber **55**. The device can include more than one single orifice or channel, in other implementations. Each orifice or channel can include a one-way valve, and can be sized and adapted for predetermined amount of blood flow.

The sequestration chamber **55** includes an air permeable blood barrier. The filter can further include a sensor or indicator to sense and/or indicate, respectively, when a predetermined volume of blood has been collected in the sequestration chamber **55**. That indication will alert a user to attach an evacuated blood collection tube or bottle, such as a Vacutainer™ to the sample needle **5**. The housing for the sequestration chamber **55** can be any size or shape, and can include any type of material to define an interior space or volume therein. The interior space is initially filled only with air, but can also be coated with an agent or substance, such as a decontaminate, solidifying agent, or the like. Once evacuated blood collection tube is attached to the sample needle **5**, blood will flow automatically into the patient needle **1**, through the blood draw channel and sample needle **5**, and into the bottle. The sample needle **5** is covered by a resealable boot, coating or membrane that seals the sample needle when a blood collection bottle is not attached thereon or thereto.

FIG. **3** illustrates a blood sample optimization system in accordance with some alternative implementations. In the implementation shown, a sample needle **5** is surrounded by a resealable boot or membrane, and is further connected with a patient needle **1**. A blood flow channel is formed through the sample needle and the patient needle. The connection between the sample needle and patient needle includes a "T" or "Y" connector **102**, which includes a channel, port or aperture leading out from the main blood flow channel to a sequestration chamber **104**.

The T or Y connector **102** may include a flap or one-way valve, and have an opening that is sized and adapted for a predetermined rate of flow of blood. The sequestration chamber **104** can be formed from tubing, or be formed by a solid housing, and is initially filled with air. The sequestration chamber **104** will receive blood that flows out of a patient automatically, i.e. under pressure from the patient's own blood pressure. The sequestration chamber **104** includes an air permeable blood barrier **106**, preferably at the distal end of tubing that forms the sequestration chamber **104**, and which is connected at the proximal end to the T or Y connector **102**. The T or Y connector **102** can branch off at any desired angle for most efficient blood flow, and can be formed so as to minimize an interface between the aperture and channel and the main blood flow channel, so as to minimize or eliminate mixing of the initial aliquot of blood with main blood draw samples.

In some alternative implementations, the sample needle may be affixed to a tubing of any length, as shown in FIG. **4**, connecting at its opposite end to the T or Y connector **102**. The sequestration chamber **104** can be any shape or volume so long as it will contain a predetermined amount of blood sample in the initial aliquot. The T or Y connector **102** may also include an opening or channel that is parallel to the main blood flow channel. The air permeable blood barrier may further include an indicator **107** or other mechanism to indicate when a predetermined amount of blood has been collected in the sequestration chamber, or when air being expelled reaches a certain threshold, i.e. to zero. The tubing can also include a clip **109** that can be used to pinch off and prevent fluid flow therethrough.

Once the air permeable blood barrier and primary chamber are sealed the initial aliquot of blood is trapped in the sequestration chamber **104**, an evacuated blood collection tube, such as a Vacutainer™ bottle may be attached to the sample needle **5** to obtain the sample. The blood collection tube can be removed, and the sample needle **5** will be resealed. Any number of follow-on blood collection tubes can then be attached for further blood draws or samples. Upon completion of all blood draws, the system can be discarded, with the initial aliquot of blood remaining trapped in the sequestration chamber **104**.

FIG. **5** illustrates a blood sample optimization system in accordance with some alternative implementations. In the implementation shown, a sample needle **5** is connected with a patient needle by tubing. A "T" or "Y" connector **120** is added along the tubing at any desired location, and includes an aperture, port or channel leading to a sequestration chamber **204**, substantially as described above.

FIG. **6** illustrates a blood sample optimization system in accordance with some alternative implementations, in which a sequestration chamber **304**, formed as a primary collection channel, receives an initial aliquot of blood, and is provided adjacent to the blood sampling channel. The sequestration chamber **304** can encircle the blood sampling channel, the patient needle **1**, and/or the sample needle **5**. The primary collection channel can include a T or Y connector **120**, or other type of aperture or channel. The sequestration chamber **304** includes an air permeable blood barrier, which can also include an indicator of being contacted by a fluid such as blood, as described above.

In some implementations, either the patient needle **1** or the sample needle **5**, or both, can be replaced by a Luer lock male or female connector. However, in various implementations, the connector at a sample needle end of the blood sample optimization system is initially sealed to permit the diversion of the initial aliquot of blood to the sequestration chamber, which is pressured at ambient air pressure and includes the air outlet of the air permeable blood barrier. In this way, the system passively and automatically uses a patient's own blood pressure to overcome the ambient air pressure of the sequestration chamber to push out air through the air permeable blood barrier and displace air in the sequestration chamber with blood.

FIG. **7** is a flowchart of an exemplary method for optimizing the quality of a blood culture. At **702**, a clinician places a needle into a patient's vein. At **704**, blood then flows into a sequestration chamber, pushing the air in the sequestration chamber out of the sequestration chamber through an air permeable blood barrier. In some implementations, the volume of the sequestration chamber is less than 0.1 to more than 5 cubic centimeters (cc's), or more. The sequestration chamber is sized and adapted to collect a first portion of a blood sample, which is more prone to contamination than secondary and other subsequent portion of the blood sample or subsequent draws. Since the sequestration chamber has an air-permeable blood barrier through which air can be displaced by blood pushed from the patient's vein, such blood will naturally and automatically flow into the sequestration chamber before it is drawn into or otherwise enters into a Vacutainer or other bottle for receiving and storing a blood sample.

When the sequestration chamber fills, the blood will gather at or otherwise make contact with the air permeable blood barrier, which will inhibit or prevent blood from passing therethrough. At **706**, when the blood comes into

contact with the entire internal surface area of the air permeable blood barrier, the air permeable blood barrier is then closed and air no longer flows out or in. At **708**, the clinician may be provided an indictor or can see the full chamber, to indicate the evacuated blood collection tube, such as a Vacutainer™ can be attached. The indicator can include visibility into the primary chamber to see whether it is full, the blood barrier changing color, for example, or other indicator. The fill time of the sequestration chamber may be substantially instantaneous, so such indicator, if present, may be only that the sequestration chamber is filled.

Prior to an evacuated blood collection tube being attached, communication between the needle, sampling channel, and the sequestration chamber is restricted by the sealing of the sequestration chamber blood barrier thereby not permitting air to reenter the system through the sequestration. Sealing the communication path could also be accomplished with a mechanical twist or other movement, a small orifice or tortuous pathway, eliminating the need for a separate valve or mechanical movement or operation by the clinician. At **710**, once the evacuated blood collection tube is removed, the self-sealing membrane closes the sample needle, and at **712**, additional subsequent evacuated blood collection tubes may be attached. Once samples have been taken, at **714** the device is removed from the patient and discarded.

FIGS. **8**A-**8**E illustrate an exemplary blood sample optimization system **800** for non-contaminated blood sampling, in accordance with some implementations. The blood sample optimization system **800** includes an inlet port **802** that can be connected to tubing, a patient needle (or both), or other vascular or venous access device, and a pathway splitter **804** having a first outlet to a sequestration chamber tubing **806** and a second outlet to sample collection tubing **808**. One or both of the sequestration chamber tubing **806** and the sample collection tubing **808** can be formed of tubing. In some implementations, the sequestration chamber tubing **806** is sized so as to contain a particular volume of initial blood sample. The sample collection tubing **808** will receive a blood sample once the sequestration chamber tubing **806** is filled. The sample collection tubing **808** can be connected to a Vacutainer™ base or housing **810**, or other blood sample collection device.

The blood sequestration system **800** further includes a blood sequestration device **812** which, as shown in more detail in FIGS. **8**B-**8**D, includes a housing **818** that includes a sampling channel **820** defining a pathway for the non-contaminated sample collection tubing **808** or connected at either end to the non-contaminated sample collection tubing **808**. The sampling channel **820** can be curved through the housing **818** so as to better affix and stabilize the housing **818** at a location along the non-contaminated sample collection tubing **808**.

The blood sequestration device **812** further includes a sequestration chamber **822** connected with the sequestration chamber tubing **806** or other chamber. The sequestration chamber **822** terminates at an air permeable blood barrier **824**. The air permeable blood barrier **824** can also include a coloring agent that turns a different color upon full contact with blood, as an indicator that the regular collection of blood samples (i.e. the non-contaminated blood samples) can be initiated. Other indicators may be used, such as a small light, a sound generation mechanism, or the like. In some implementations, the air permeable blood barrier is positioned at a right angle from the direction of sequestration chamber **822**, but can be positioned at any distance or orientation in order to conserve space and materials used for the housing **818**. The housing **818** and its contents can be formed of any rigid or semi-rigid material or set of materials.

FIG. **9** illustrates a pathway splitter **900** for use in a blood sequestrations system, such as those shown in FIGS. **8**A-**8**E, for example. The pathway splitter **900** includes an inlet port **902**, a main line outlet port **904**, and a sequestration channel outlet port **906**. The inlet port **902** can be connected to main tubing that is in turn connected to a patient needle system, or directly to a patient needle. The main line outlet port **904** can be connected to main line tubing to a blood sampling system, such as a vacutainer base or housing, or directly to such blood sampling system. The sequestration channel outlet port **906** can be connected to sequestration tubing for receiving and sequestering a first sample of blood, up to a measured amount or predetermined threshold. Alternatively, the sequestration channel outlet port **906** can be connected to a sequestration chamber. The sequestration channel outlet port **906** is preferably 20-70 degrees angled from the main line outlet port **904**, which in turn is preferably in-line with the inlet port **902**. Once the predetermined amount of initial blood sample is sequestered in the sequestration tubing or chamber, in accordance with mechanisms and techniques described herein, follow-on blood samples will flow into the inlet port **902** and directly out the main line outlet port **904**, without impedance.

FIGS. **10**A-**10**D illustrate a blood sequestration device **1000** in accordance with alternative implementations. The blood sequestration device **1000** includes an inlet port **1002**, a main outlet port **1004**, and a sequestration channel port **1006**. The inlet port **1002** can be connected to a patient needle or related tubing. The main outlet port **1004** can be connected to a blood sample collection device such as a Vacutainer, associated tubing, or a Luer activated valve, or the like. The sequestration channel port **1006** splits off from the main outlet port **1004** to a sequestration chamber **1008**. In some implementations, the sequestration chamber **1008** is formed as a helical channel within a housing or other container **1001**.

The sequestration chamber **1008** is connected at the distal end to an air permeable blood barrier **1010**, substantially as described above. Air in the sequestration chamber **1008** is displaced through the air permeable blood barrier **1010** by an initial aliquot of blood that is guided into the sequestration channel port **1006**. Once the sequestration chamber **1008** is filled, further blood draws through the main outlet port **1004** can be accomplished, where these samples will be non-contaminated.

FIGS. **11**A-**11**E illustrate a blood sequestration device **1100** in accordance with other alternative implementations. The blood sequestration device **1100** includes an inlet port **1102**, similar to the inlet ports described above, a main outlet port **1104**, and a sequestration channel port **1106** that splits off from the main outlet port **1104** and inlet port **1102**. The sequestration channel port is connected to a sequestration chamber **1108**. In the implementation shown in FIGS. **11**A-**11**E, the blood sequestration device includes a base member **1101** having a channel therein, which functions as the sequestration chamber **1108**. The channel can be formed as a tortuous path through the base member **1101**, which is in turn shaped and formed to rest on a limb of a patient.

A portion of the sequestration chamber **1108** can protrude from the base member or near a top surface of the base member, just before exiting to an air permeable blood barrier **1110**, to serve as a blood sequestration indicator **1109**. The indicator **1109** can be formed of a clear material, or a material that changes color when in contact with blood.

In some implementations, the blood sequestration device **1100** can include a blood sampling device **1120** such as a normally closed needle, Vacutainer™ shield or other collection device. The blood sampling device **1120** can be manufactured and sold with the blood sequestration device **1100** for efficiency and convenience, so that a first aliquot of blood that may be contaminated by a patient needle insertion process can be sequestered. Thereafter, the blood sampling device **1120** can draw non-contaminated blood samples to reduce the risk of false positive testing and ensure a non-contaminated sample.

FIGS. **12**A-**12**D illustrate a blood sample optimization system **1200** in accordance with yet other alternative implementations. The system **1200** includes a blood sequestration device **1202** for attaching to a blood sampling device **1204**, such as a Vacutainer™ or other collection and sampling device. The blood sequestration device **1202** is configured and arranged to receive, prior to a Vacutainer™ container or vial being attached to a collection needle of the blood sampling device **1204**, a first aliquot or amount of blood, and sequester that first aliquot or amount in a sequestration channel of the blood sequestration device **1202**.

In some implementations, the blood sequestration device **1202** can include an inlet port **1212**, a main outlet port, and a sequestration channel port. The inlet port **1212** can be connected to a patient needle or related tubing. The main outlet port **1214** can be connected to a normally closed needle or device to enable connection with an evacuated blood collection container or other collection device such as a Vacutainer™, associated tubing, luer connectors, syringe, a Luer activated valve, or the like. The sequestration channel port splits off from the main outlet port to a sequestration chamber **1218**.

In some implementations, the sequestration chamber **1218** is formed as a channel within the body of a sequestration device **1202**. The sequestration chamber **1218** can be a winding channel, such as a U-shaped channel, an S-shaped channel, a helical channel, or any other winding channel. The sequestration device **1202** can include a housing or other containing body, and one or more channels formed therein. As shown in FIGS. **12**A and **12**B, the sequestration device **1202** includes a main body **1206** and a cap **1208**. The main body **1206** is formed with one or more cavities or channels, which are further formed with one or more arms **1210** that extend from the cap **1208**, and which abut the cavities or channels in the main body **1206** to form the primary collection port and main outlet port.

FIGS. **13**A-**13**D illustrate a blood sample optimization system **1300** in accordance with yet other alternative implementations. The system **1300** includes a blood sequestration device **1302** for attaching to a blood sampling device **1304**, such as a Vacutainer or other bodily fluid collection and sampling device. The blood sequestration device **1302** is configured and arranged to receive, prior to a Vacutainer container or vial being attached to a collection needle of the blood sampling device **1304**, a first aliquot or amount of blood, and to sequester that first aliquot or amount of blood or other bodily fluid in a sequestration channel of the blood sequestration device **1302**.

The blood sequestration device **1302** includes a housing **1301** having an inlet port **1314**, a main outlet port **1312**, and a sequestration channel port **1316**. The inlet port **1314** can be connected to a patient needle or associated tubing. The main outlet port **1312** can be connected to a normally closed needle or device to enable connection with an evacuated blood collection container or other collection device such as a Vacutainer™, associated tubing, luer connectors, syringe, a Luer activated valve, or the like. The sequestration channel port **1316** splits off from the main inlet port **1314** to a sequestration chamber **1318**.

In the implementation shown in FIGS. **13**A-D, the sequestration chamber **1318** is formed as a cavity or chamber within housing **1301** or formed by walls that define housing **1301**. The sequestration chamber **1318** can be a winding channel, such as a U-shaped channel, an S-shaped channel, a helical channel, or any other winding channel, that is defined by the cooperation and connection of housing **1301** with cap **1307** which cap **1307** can include a protrusion **1305** that provides one or more walls or directors for the winding channel in the sequestration chamber **1318**. The protrusion **1305** from the cap **1307** can be straight or curved, and may have various channels, apertures or grooves embedded therein, and can extend from the cap **1307** any angle or orientation. When the cap **1307** is connected with the housing **1301** to complete the formation of the sequestration chamber **1318**, the protrusion **1305** forms at least part of the winding channel to sequester a first aliquot or amount of blood or other bodily fluid in a sequestration channel formed in the sequestration chamber **1318** and by the winding channel.

The sequestration chamber **1318** includes an air permeable blood barrier **1310**, substantially as described above. Air in the sequestration chamber **1318** is displaced through the air permeable blood barrier **1310** by an initial aliquot of blood that is provided into the sequestration chamber **1318** by the blood pressure of the patient. Once the sequestration chamber **1318** is filled and the air in the sequestration chamber **1318** displaced, the blood pressure of the patient will be insufficient to drive or provide further blood into the blood sequestration device **1302**, and in particular the outlet port **1312**, until a force such as a vacuum or other pressure, such as provided by the blood sample collection device like Vacutainer is provided to draw out a next aliquot or amount of blood or bodily fluid. Further blood draws through the main outlet port **1312** can be accomplished, where these samples will be non-contaminated since any contaminants would be sequestered in the sequestration chamber **1318** with the first aliquot of blood.

FIGS. **14**A-**14**E illustrate yet another implementation of a blood sampling system **1400** to sequester contaminates of an initial aliquot or sample to reduce false positives in blood cultures or tests performed on a patient's blood sample. The blood sampling system **1400** includes a blood sequestration device **1401** that can be connected between a blood sample collection device **1403** and a patient needle (not shown). The blood sample collection device **1403** can be a Vacutainer or the like. The blood sequestration device **1401** includes an inlet port **1402** that can be connected with a patient needle that is inserted into a patient's vascular system for access to and withdrawing of a blood sample. The inlet port **1402** may also be connected with tubing or other conduit that is in turn connected with the patient needle.

The inlet port **1402** defines an opening into the blood sequestration device **1401**, which opening can be the same cross sectional dimensions as tubing or other conduit connected with the patient needle or the patient needle itself. For instance, the opening can be circular with a diameter of approximately 0.045 inches, but can have a diameter of between 0.01 inches or less to 0.2 inches or more. The blood sequestration device **1401** further includes an outlet port **1404**, which defines an opening out of the blood sequestration device **1401** and to the blood sample collection device **1403**. The outlet port **1404** may also be connected with tubing or other conduit that is in turn connected with the

blood sequestration device **1403**. The outlet port **1404** can further include a connector device such as a threaded cap, a Luer connector (male or female), a non threaded interference or glue joint fitting for attachment of various devices including but not limited to tubing, or the like.

The blood sequestration device **1401** further includes a sampling channel **1406** between the inlet port **1402** and the outlet port **1404**, and which functions as a blood sample pathway once a first aliquot of blood has been sequestered. The sampling channel **1406** can be any sized, shaped or configured channel, or conduit. In some implementations, the sampling channel **1406** has a substantially similar cross sectional area as the opening of the inlet port **1402**. In other implementations, the sampling channel **1406** can gradually widen from the inlet port **1402** to the outlet port **1404**.

The blood sequestration device **1401** further includes a sequestration chamber **1408** that is connected to and split off or diverted from the sampling channel **1406** at any point between the inlet port **1402** and the outlet port **1404**, but preferably from a proximal end of the sampling channel **1406** near the inlet port **1402**. The sequestration chamber **1408** is at first maintained at atmospheric pressure, and includes an air outlet **1412** at or near a distal end of the sequestration chamber **1408** opposite the diversion point from the sampling channel **1406**. The air outlet **1412** includes an air permeable blood barrier **1412**. As shown in FIG. **14**B, the air permeable blood barrier **1412** can be overlaid with a protective cover **1416**. The protective cover **1416** can be sized and configured to inhibit a user from touching the air permeable blood barrier **1412** with their finger or other external implement, while still allowing air to exit the air permeable blood barrier **1412** as the air is displaced from the sequestration chamber **1408** by blood being forced into the sequestration chamber **1408** by a patient's own blood pressure. In addition the protective cover **1416** can be constructed to inhibit or prevent accidental exposure of the air permeable blood barrier to environmental fluids or splashes. This can be accomplished in a variety of mechanical ways including but not limited to the addition of a hydrophobic membrane to the protective cover.

As shown in FIGS. **14**C and **14**D, the sampling channel **1406** can be cylindrical or frusto-conical in shape, going from a smaller diameter to a larger diameter, to minimize a potential to lyse red blood cells. Likewise, the sampling channel **1406** is formed with a minimal amount of or no sharp turns or edges, which can also lyse red blood cells. The sampling channel **1406** splits off to the sequestration chamber **1408** near the inlet port **1402** via a diversion pathway **1409**. The diversion pathway **1409** can have any cross-sectional shape or size, but is preferably similar to the cross-sectional shape of at least part of the inlet port **1402**.

In some implementations, the sampling channel **1406** and the sequestration chamber **1408** are formed by grooves, channels, locks or other pathways formed in housing **1414**. The housing **1414** can be made of plastic, metal or other rigid or semi-rigid material. The housing **1414** can have a bottom member that sealably mates with a top member. One or both of the bottom member and the top member can include the sampling channel **1406** and the sequestration chamber **1408**, as well as the diversion pathway **1409**, the inlet port **1402**, and the outlet port **1404**. In some other implementations, one or more of the diversion pathway **1409**, the inlet port **1402**, and/or the outlet port **1404** can be at least partially formed by a cap member that is connected to either end of the housing **1414**. In some implementations, the top member and the bottom member, as well as the cap member(s), can be coupled together by laser welding, heat sealing, gluing, snapping, screwing, bolting, or the like. In other implementations, some or all of the interior surface of the diversion pathway **1409** and/or sequestration chamber **1408** can be coated or loaded with an agent or substance, such as a decontaminate, solidifying agent, or the like. For instance, a solidifying agent can be provided at the diversion pathway **1409** such that when the sequestration chamber **1408** is filled and the initial aliquot of blood backs up to the diversion pathway **1409**, that last amount of sequestered blood could solidify, creating a barrier between the sequestration chamber **1408** and the sampling channel **1406**.

FIGS. **15**A-**15**G illustrate a blood sequestration device **1500**. The blood sequestration device **1500** can be connected to a normally closed needle or device to enable connection with an evacuated blood collection container or other collection device such as a Vacutainer™, associated tubing, luer connectors, syringe, a Luer activated valve, or the like.

The blood sequestration device **1500** includes an inlet port **1502** that can be connected with a patient needle that is inserted into a patient's vascular system for access to and withdrawing of a blood sample. The inlet port **1502** may also be connected with tubing or other conduit that is in turn connected with the patient needle. The inlet port **1502** defines an opening into the blood sequestration device **1500**, which opening may be the same cross sectional dimensions as tubing or other conduit connected with the patient needle or the patient needle itself. For instance, the opening can be circular with a diameter of approximately 0.045 inches, but can have a diameter of between 0.01 inches or less to 0.2 inches or more.

The inlet port **1502** can also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. In some implementations, tubing or other conduit associated with the patient needle can be integral with the inlet port **1502**, such as by co-molding, gluing, laser weld, or thermally bonding the parts together. In this manner, the blood sequestration device **1500** can be fabricated and sold with the patient needle as a single unit, eliminating the need for connecting the patient needle to the blood sequestration device **1500** at the time of blood draw or sampling.

The blood sequestration device **1500** further includes an outlet port **1504**, which defines an opening out of the blood sequestration device **1500** and to the blood sample collection device. The outlet port **1504** may also be connected with tubing or other conduit that is in turn connected with the blood sequestration device, and may also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. Accordingly, as discussed above, the blood sequestration device **1500** can be fabricated and sold with the patient needle and/or tubing and the blood sample collection device as a single unit, eliminating the need for connecting the patient needle and the blood sample collection device to the blood sequestration device **1500** at the time of blood draw or sampling.

The blood sequestration device **1500** further includes a sampling channel **1506** between the inlet port **1502** and the outlet port **1504**, and which functions as a blood sample pathway once a first aliquot of blood has been sequestered. The sampling channel **1506** can be any sized, shaped or configured channel or conduit. In some implementations, the sampling channel **1506** has a substantially similar cross sectional area as the opening of the inlet port **1502**. In other implementations, the sampling channel **1506** can gradually widen from the inlet port **1502** to the outlet port **1504**.

The blood sequestration device **1500** further includes a sequestration chamber **1508** that is connected to and split off or diverted from the sampling channel **1506** at any point

between the inlet port **1502** and the outlet port **1504**, but preferably from a proximal end of the sampling channel **1506** near the inlet port **1502**. In some implementations, the diversion includes a Y-shaped junction. The sequestration chamber **1508** is preferably maintained at atmospheric pressure, and includes a vent **1510** at or near a distal end of the sequestration chamber **1508**. The vent **1510** includes an air permeable blood barrier **1512**. FIG. **15**C illustrates the blood sequestration device **1500** with the sequestration chamber **1508** filled with a first aliquot or sample of blood from the patient.

The air permeable blood barrier **1512** can be covered with a protective cover **1516**. The protective cover **1516** can be sized and configured to inhibit a user from touching the air permeable blood barrier **1512** with their finger or other external implement, while still allowing air to exit the air permeable blood barrier **1512** as the air is displaced from the sequestration chamber **1508** by blood being forced into the sequestration chamber **1508** by a patient's own blood pressure. The protective cover **1516** can be constructed to inhibit or prevent accidental exposure of the filter to environmental fluids or splashes. This can be accomplished in a variety of mechanical ways including but not limited to the addition of a hydrophobic membrane to the protective cover.

FIG. **15**B is a perspective view of the blood sequestration device **1500** from the outlet port **1504** and top side of a housing **1501** of the blood sequestration device **1500** that includes the vent **1510**, and illustrating an initial aliquot of blood filling sequestration chamber **1508** while the sampling channel **1506** is empty, before a sample collection device is activated. FIG. **15**G is a perspective view of the blood sequestration device **1500** from the outlet port **1504** and bottom side of the housing **1501** of the blood sequestration device **1500**, and illustrating the initial aliquot of blood filling sequestration chamber **1508** while the sampling channel **1506** is empty, before the sample collection device is activated. FIG. **15**C is another perspective view of the blood sequestration device **1500** from the inlet port **1502** and top side of a housing **1501** of the blood sequestration device **1500** that includes the vent **1510**, and illustrating blood now being drawn through sampling channel **1506** while the sequestered blood remains substantially in the sequestration chamber **1508**.

FIG. **15**D is a cross section of the blood sequestration device **1500** in accordance with some implementations, showing the housing **1501** that defines the sampling channel **1506** and the sequestration chamber **1508**. FIGS. **15**E and **15**F illustrate various form factors of a housing for a blood sequestration device, in accordance with one or more implementations described herein.

The sequestration chamber **1508** can have a larger cross-sectional area than the sampling channel **1506**, and the cross-sectional area and length can be configured for a predetermined or specific volume of blood to be sequestered or locked. The sampling channel **1506** can be sized to be compatible with tubing for either or both of the patient needle tubing or the blood collection device tubing.

The housing **1501** can be formed of multiple parts or a single, unitary part. In some implementations, and as illustrated in FIG. **15**D, the housing **1501** includes a top member **1520** and a bottom member **1522** that are mated together, one or both of which having grooves, channels, locks, conduits or other pathways pre-formed therein, such as by an injection molding process or by etching, cutting, drilling, etc. The top member **1520** can be connected with the bottom member **1522** by any mating or connection mechanism, such as by laser welding, thermal bonding, ultrasonic welding, gluing, using screws, rivets, bolts, or the like, or by other mating mechanisms such as latches, grooves, tongues, pins, flanges, or the like.

In some implementations, such as shown in FIG. **15**D, the top member **1520** can include the grooves, channels, locks, conduits or other pathways, while the bottom member **1522** can include a protrusion **1524** that is sized and adapted to fit into at least one of the grooves, channels, locks or other pathways of the top member **1520**. The protrusion **1524** can provide a surface feature, such as a partial groove or channel, for instance, to complete the formation of either the sampling channel **1506** and/or the sequestration chamber **1508**. In some implementations, the protrusion **1524** can be formed with one or more angled sides or surfaces for a tighter fit within the corresponding groove, channel, lock or other pathway. In yet other implementations, both the top member **1520** and the bottom member can include grooves, channels, locks or other pathways, as well as one or more protrusions **1524**.

In some implementations, the sampling channel **1506** and the sequestration chamber **1508** are formed by grooves, channels, locks or other pathways formed in housing **1501**. The housing **1501** can be made of any suitable material, including rubber, plastic, metal or other material. The housing **1501** can be formed of a clear or translucent material, or of an opaque or non-translucent material. In other implementations, the housing **1501** can be mostly opaque or non-translucent, while the housing surface directly adjacent to the sampling channel **1506** and/or the sequestration chamber **1508** is clear or translucent, giving a practitioner a visual cue or sign that the sequestration chamber **1508** is first filled to the extent necessary or desired, and/or then a visual cue or sign that the sequestered blood remains sequestered while a clean sample of blood is drawn through the sampling channel **1506**. Other visual cues or signs of the sequestration can include, without limitation: the air permeable blood barrier **1512** turning a different color upon contact, saturation, or partial saturation with blood; a color-coded tab or indicator at any point along or adjacent to the sequestration chamber; an audible signal; a vibratory signal; or other signal.

After a venipuncture by a patient needle of a patient (not shown), which could gather a number of pathogens from the patient's skin, a first amount of the patient's blood with those pathogens will make its way into the input port **1502** blood sequestration device **1500** and flow into the sequestration chamber **1508** by following the path of least resistance, as the patient's own blood pressure overcomes the atmospheric pressure in the sequestration chamber **1508** to displace air therein through the air permeable blood barrier **1512**. The patient's blood pressure will not be sufficient to overcome the air pressure that builds up in the sealed sampling channel **1506**. Eventually, the sequestration chamber **1508**, which has a predetermined volume, is filled with blood that displaces air through the air permeable blood barrier **1512**. Once the blood hits the air permeable blood barrier, the blood interacts with the air permeable blood barrier **1512** material to completely or partially seal the vent **1510**. A signal or indication may be provided that the practitioner can now utilize the Vacutainer capsule or other blood sample collection device to acquire a next amount of the patient's blood for sampling. The blood in the sequestration chamber **1508** is now effectively sequestered in the sequestration chamber.

Upon filling the blood sequestration pathway **1508** but prior to use of the Vacutainer or other blood sample collection device, the patient's blood pressure may drive com-

pression of the air in the sampling channel **1506**, possibly resulting in a small amount of blood moving past the diversion point to the sequestration chamber **1508** and into the sampling channel **1506**, queuing up the uncontaminated blood to be drawn through the sampling channel **1506**.

FIGS. **16-19** illustrate yet another implementation of a blood sequestration device. FIGS. **16**A-**16**D illustrate a blood sequestration device **1600** that can be connected between a blood sample collection device, such as an evacuated blood collection container like a Vacutainer™ (not shown), and a patient needle (not shown) and/or associated tubing. FIG. **17** illustrates a bottom member of the blood sequestration device, and FIG. **18** illustrates a top member of the blood sequestration device, which top member and bottom member can be mated together to form an input port, and output port, a sequestration chamber and a sampling channel, as explained more fully below. FIGS. **19**A and B show the top member and bottom member mated together. It should be understood that FIGS. **16-19** illustrate one exemplary manner of constructing a blood sequestration device as described herein, and other forms of construction are possible.

Referring to FIGS. **16**A-D, the blood sequestration device **1600** includes an inlet port **1602** that can be connected with a patient needle that is inserted into a patient's vascular system for access to and withdrawing of a blood sample. The inlet port **1602** may also be connected with tubing or other conduit that is in turn connected with the patient needle. The inlet port **1602** defines an opening into the blood sequestration device **1600**, which opening can be the same cross sectional dimensions as tubing or other conduit connected with the patient needle or the patient needle itself. For instance, the opening can be circular with a diameter of approximately 0.045 inches, but can have a diameter of between 0.01 inches or less to 0.2 inches or more.

The inlet port **1602** can also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. In some implementations, tubing or other conduit associated with the patient needle can be integral with the inlet port **1602**, such as by co-molding, gluing, laser weld, or thermally bonding the parts together. In this manner, the blood sequestration device **1600** can be fabricated and sold with the patient needle and/or tubing as a single unit, eliminating the need for connecting the patient needle to the blood sequestration device **1600** at the time of blood draw or sampling.

The blood sequestration device **1600** further includes an outlet port **1604**, which defines an opening out of the blood sequestration device **1600** and to the blood sample collection device. The outlet port **1604** may also be connected with tubing or other conduit that is in turn connected with the blood sequestration device, and may also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. Accordingly, as discussed above, the blood sequestration device **1600** can be fabricated and sold with the patient needle and/or tubing and the blood sample collection device as a single unit, eliminating the need for connecting the patient needle and the blood sample collection device to the blood sequestration device **1600** at the time of blood draw or sampling.

The blood sequestration device **1600** further includes a sampling channel **1606** between the inlet port **1602** and the outlet port **1604**, and a sequestration chamber **1608** that is connected to and split off or diverted from the sampling channel **1606** at any point between the inlet port **1602** and the outlet port **1604**. The sampling channel **1606** functions as a blood sampling pathway once a first aliquot of blood has been sequestered in the sequestration chamber **1608**. The sampling channel **1606** can be any sized, shaped or configured channel, or conduit. In some implementations, the sampling channel **1606** has a substantially similar cross sectional area as the opening of the inlet port **1602**. In other implementations, the sampling channel **1606** can gradually widen from the inlet port **1602** to the outlet port **1604**. The sequestration chamber **1608** may have a larger cross section to form a big reservoir toward the sequestration channel path so that the blood will want to enter the reservoir first versus entering a smaller diameter on the sampling channel **1606**, as is shown more fully in FIGS. **17** and **19**.

In some exemplary implementations, the diversion between the sampling channel **1606** and the sequestration chamber **1608** is by diverter junction **1607**. Diverter junction **1607** may be a substantially Y-shaped, T-shaped, or U-shaped. In some preferred exemplary implementations, and as shown in FIG. **17**A-**17**B, the diverter junction **1607** is configured such that the flow out of the inlet port **1602** is preferentially directed toward the sequestration chamber **1608**. The sequestration chamber **1608** may also include or form a curve or ramp to direct the initial blood flow toward and into the sequestration chamber **1608**.

The sequestration chamber **1608** is preferably maintained at atmospheric pressure, and includes a vent **1610** at or near a distal end of the sequestration chamber **1608**. The vent **1610** may include an air permeable blood barrier **1612** as described above.

The blood sequestration device **1600** can include a housing **1601** that can be formed of multiple parts or a single, unitary part. In some implementations, and as illustrated in FIGS. **17**A-**17**D and FIGS. **18**A-**18**F, the housing **1601** includes a top member **1620** and a bottom member **1622** that are mated together. The blood sequestration device **1600** can also include a gasket or other sealing member (not shown) so that when the top member **1620** is mechanically attached with the bottom member **1622**, the interface between the two is sealed by the gasket or sealing member. The FIGS. **17**A-**17**D illustrate a bottom member **1622** of a housing for a blood sequestration device **1600**. The bottom member **1622** can include grooves, channels, locks, conduits or other pathways pre-formed therein, such as by an injection molding process or by etching, cutting, drilling, etc., to form the sampling channel **1606**, the sequestration chamber **1608**, and diverter junction **1607**.

The sequestration chamber **1608** may have a larger cross section than the sampling channel **1606** so that the blood will preferentially move into the sequestration chamber first versus entering a smaller diameter on the sampling channel **1606**.

FIGS. **18**A-**18**F illustrate the top member **1620**, which can be connected with the bottom member **1622** by any mating or connection mechanism, such as by laser welding, thermal bonding, gluing, using screws, rivets, bolts, or the like, or by other mating mechanisms such as latches, grooves, tongues, pins, flanges, or the like. The top member **1620** can include some or all of the grooves, channels, locks, conduits or other pathways to form the sampling channel **1606**, the sequestration chamber **1608**, and the diverter junction **1607**. In yet other implementations, both the top member **1620** and the bottom member **1622** can include the grooves, channels, locks or other pathways.

In some implementations, the sampling channel **1606** and the sequestration chamber **1608** are formed by grooves, channels, locks or other pathways formed in housing **1601**. The housing **1601** can be made of rubber, plastic, metal or any other suitable material. The housing **1601** can be formed

of a clear or translucent material, or of an opaque or non-translucent material. In other implementations, the housing **1601** can be mostly opaque or non-translucent, while the housing surface directly adjacent to the sampling channel **1606** and/or the sequestration chamber **1608** may be clear or translucent, giving a practitioner a visual cue or sign that the sequestration chamber **1608** is first filled to the extent necessary or desired, and/or then a visual cue or sign that the sequestered blood remains sequestered while a clean sample of blood is drawn through the sampling channel **1606**. Other visual cues or signs of the sequestration can include, without limitation: the air permeable blood barrier **1612** turning a different color upon contact, saturation, or partial saturation with blood; a color-coded tab or indicator at any point along or adjacent to the sequestration chamber; an audible signal; a vibratory signal; or other signal.

As shown in FIGS. **18A-18F**, the air permeable blood barrier **1612** can be covered with, or surrounded by, a protective member **1616**. The protective member **1616** can be sized and configured to inhibit a user from touching the air permeable blood barrier **1612** with their finger or other external implement, while still allowing air to exit the air permeable blood barrier **1612** as the air is displaced from the sequestration chamber **1608**. In some implementations, the protective member **1616** includes a protrusion that extends up from a top surface of the top member **1620** and around the air permeable blood barrier **1612**. The protective cover **1616** can be constructed to inhibit or prevent accidental exposure of the filter to environmental fluids or splashes. This can be accomplished in a variety of mechanical ways including but not limited to the addition of a hydrophobic membrane to the protective cover.

In use, the blood sequestration device **1600** includes a sampling channel **1606** and a sequestration chamber **1608**. Both pathways are initially air-filled at atmospheric pressure, but the sampling channel **1606** is directed to an output port **1604** that will be initially sealed by a Vacutainer or other such sealed blood sampling device, and the sequestration chamber **1608** terminates at a vent **1610** to atmosphere that includes an air permeable blood barrier **1612**.

After a venipuncture by a patient needle of a patient (not shown), which could gather a number of pathogens from the patient's skin, a first amount of the patient's blood with those pathogens will pass through input port **1602** of blood sequestration device **1600**. This initial volume of potentially contaminated blood will preferentially flow into the sequestration chamber **1608** by finding the path of least resistance. The patient's own blood pressure overcomes the atmospheric pressure in the vented sequestration chamber **1608** to displace air therein through the air permeable blood barrier **1612**, but is not sufficient to overcome the air pressure that builds up in the sealed sampling channel **1606**. In various exemplary embodiments, the sequestration chamber **1608** and sampling channel **1606** can be configured such that the force generated by the patient's blood pressure is sufficient to overcome any effect of gravity, regardless of the blood sequestration device's orientation.

Eventually, the sequestration chamber **1608** fills with blood that displaces air through the air permeable blood barrier **1612**. Once the blood contacts the air permeable blood barrier, the blood interacts with the air permeable blood barrier **1612** material to completely or partially seal the vent **1610**. A signal or indication may be provided that the practitioner can now utilize the Vacutainer or other blood sampling device.

Upon filling the blood sequestration pathway **1608** but prior to use of the Vacutainer or other blood sample collection device, the patient's blood pressure may drive compression of the air in the sampling channel **1606**, possibly resulting in a small amount of blood moving past the diversion point into the sampling channel **1606**, queuing up the uncontaminated blood to be drawn through the sampling channel **1606**.

FIG. **19A** is a side view, and FIG. **19B** is a cross-sectional view, of the blood sequestration device **1600**, illustrating the top member **1620** mated with the bottom member **1622**.

FIG. **20** shows a blood sample optimization system **2000** that includes a patient needle **2002** for vascular access to a patient's bloodstream, a blood sample collection device **2004** to facilitate the collecting of one or more blood samples, and a conduit **2006** providing a fluid connection between the patient needle **2002** and the blood sample collection device **2004**. In some implementations, the blood sample collection device **2004** includes a protective shield that includes a sealed collection needle on which a sealed vacuum-loaded container is placed, which, once pierced by the collection needle, draws in a blood sample under vacuum pressure or force through the conduit **2006** from the patient needle **2002**.

The blood sample optimization system **2000** further includes a blood sequestration device **2008**, located at any point on the conduit **2006** between the patient needle **2002** and the blood sample collection device **2004** as described herein.

FIG. **21** illustrates a non-vented blood sequestration device **2100** using a wicking material chamber. The blood sequestration device **2100** includes a housing **2101** that has a sampling channel **2104** that is at least partially surrounded or abutted by a sequestration chamber **2102** that is filled with a wicking material. An initial aliquot of blood is drawn in from the patient needle into the sampling channel **2104** where it is immediately wicked into the wicking material of the sequestration chamber **2102**. The wicking material and/or sequestration chamber **2102** is sized and adapted to receive and hold a predetermined amount of blood, such that follow-on or later blood draws pass by the wicking material and flow straight through the sampling channel **2104** to a sampling device such as a Vacutainer. The wicking material can include a substance such as a solidifier, a decontaminate, or other additive.

As described herein, an air permeable blood barrier may be created using a wide variety of different structures and materials. As shown in FIGS. **22A** and B, an air permeable blood barrier **2202** of a blood sequestration device **2200** can include a polymer bead matrix **2204**, in which at least some beads are treated to make them hydrophilic. The air permeable blood barrier **2202** further includes a self-sealing material **2206**, such as carboxymethyl cellulose (CMC) or cellulose gum, or other sealing material. The air permeable blood barrier **2202** can further include voids **2208** that permit air flow before contact or during partial contact with a fluid such as blood. As shown in FIG. **22B**, contact with a fluid causes the self-sealing material **2206** to swell and close off the voids **2208**, occluding air flow through the voids **2208** and creating a complete or partial seal.

FIGS. **23A** and B illustrate yet another implementation of a blood sequestration device **2300**, having an inlet port **2302** to connect with a patient needle, an outlet port **2304** to connect with a blood sample collection device, a sequestration chamber **2306**, and a sampling channel **2308** that bypasses the sequestration chamber **2306** once the sequestration chamber is filled to an initial aliquot of potentially contaminated blood to be sequestered. The sequestration chamber **2306** includes a hydrophobic plug **2312** at a distal

end of the sequestration chamber **2306** that is farthest from the inlet port **2302**. A vacuum or other drawing force applied from the outlet port **2304**, such as from a Vacutainer or the like, draws in blood into the inlet port **2302** and directly into the sequestration chamber **2306**, where the initial aliquot of blood will contact the hydrophobic plug **2312** and cause the initial aliquot of blood to back up into the sequestration chamber **2306** and be sequestered there. A small amount of blood may make its way into the sampling channel **2308**, which is initially closed off by valve **2308**. Upon release of the valve **2308**, and under further force of the vacuum or other force, follow-on amounts of blood will flow into inlet port **2302**, bypass the sequestration chamber **2306**, and flow into and through sampling channel **2308** toward the outlet port **2304** and to the collection device.

The sampling channel **2308** can have any suitable geometry and can be formed of plastic tubing or any other suitable material. Valve **2308** can be a clip or other enclosing device to pinch, shunt, bend or otherwise close off the sampling channel before the initial aliquot of blood is sequestered in the sequestration chamber **2306**.

Although a variety of embodiments have been described in detail above, other modifications are possible. Other embodiments may be within the scope of the following claims.

The invention claimed is:

1. A blood sample optimization system comprising:

a blood sampling system comprising:

a patient needle configured for a venipuncture of a patient to access a sample of blood of a patient;

a blood sampling pathway connected with the patient needle configured for conveying the sample of blood; and

a sample needle configured for receiving an evacuated blood collection tube to collect and contain a subsequent portion of the sample of blood; and

a blood sequestration device connected along the blood sampling pathway between the patient needle and the sample needle, the blood sequestration device comprising;

an inlet port configured for receiving the sample of blood;

a sequestration chamber connected with the inlet port configured for receiving a first amount of the sample of blood, the sequestration chamber having a vent comprising an air permeable blood barrier configured for sequestering at least a first portion of the first amount of the sample of blood;

a sampling channel having a proximal end connected with the inlet port configured for receiving the subsequent portion of the sample of blood,

wherein the sequestration chamber, the sampling channel and the inlet port being configured to allow the subsequent portion of the sample of blood to bypass the sequestration chamber and the first portion of the blood sequestered therein, and direct the subsequent portion of the sample of blood toward an outlet port, connected with a distal end of the sampling channel, the outlet port configured for outputting the subsequent portion of the sample of blood to the evacuated blood collection tube; and

further comprising a housing that houses and defines the inlet port, the outlet port, the sequestration chamber and the sampling channel.

2. The blood sample optimization system in accordance with claim **1**, wherein the sequestration chamber of the blood sequestration device is at ambient air pressure, and wherein the sequestration chamber receives the first portion of the blood sample by blood pressure of the patient overcoming the ambient air pressure in the sequestration chamber.

3. The blood sample optimization system in accordance with claim **2**, wherein the sample needle includes a seal that is pierced by the evacuated blood collection tube to open access to the patient needle via the blood sampling pathway and the sampling channel.

4. The blood sample optimization system in accordance with claim **3**, wherein the sampling channel of the blood sequestration device causes the subsequent portion of the blood sample to enter the inlet port under vacuum pressure by the evacuated blood collection tube that unseals the sample needle.

5. The blood sample optimization system in accordance with claim **1**, wherein the air permeable blood barrier of the blood sequestration device includes an air permeable material that seals upon contact with blood.

6. The blood sample optimization system in accordance with claim **1**, wherein the blood sampling pathway of the blood sampling system comprises tubing.

7. A blood sequestration device connected with a blood sampling system comprising a patient needle configured for accessing a blood sample from a patient, and a sample needle that is sealed and adapted for receiving an evacuated blood collection tube to unseal the sample needle and draw the accessed blood sample from the patient, the blood sequestration device comprising;

an inlet port connected with the patient needle configured to receive the blood sample from the patient; an outlet port connected with the inlet port;

a sequestration chamber connected with the inlet port and having a vent comprising an air permeable blood barrier, the sequestration chamber configured for receiving and sequestering a first portion of the blood sample prior to the sample needle being unsealed by the evacuated blood collection tube;

a sampling channel having a proximal end connected with the inlet port configured for receiving a subsequent portion of the blood sample,

wherein the sequestration chamber, the sampling channel and the inlet port being configured to allow the subsequent portion of the blood sample to bypass the sequestration chamber and the first portion of the blood sample sequestered therein, and direct the subsequent portion of the sample of blood toward the outlet port, wherein the outlet port is connected with a distal end of the sampling channel; and further comprising a housing that houses and defines the inlet port, the outlet port, the sequestration chamber and the sampling channel.

8. The blood sequestration device in accordance with claim **7**, wherein the sequestration chamber is at ambient air pressure, and wherein the sequestration chamber receives the first portion of the blood sample by blood pressure of the patient overcoming the ambient air pressure in the sequestration chamber.

9. The blood sequestration device in accordance with claim **7**, wherein the air permeable blood barrier includes an air permeable material that seals upon contact with blood.

10. The blood sequestration device in accordance with claim **7**, wherein the sequestration chamber includes a sequestration channel defined in the housing.

11. A blood sample optimization system comprising:

a blood sampling system comprising:

a patient needle configured for a venipuncture of a patient to access a sample of blood of a patient;

a blood sampling pathway connected with the patient needle configured for conveying the sample of blood; and

a sample needle configured for receiving an evacuated blood collection tube to collect and contain a subsequent portion of the sample of blood; and

a blood sequestration device connected along the blood sampling pathway between the patient needle and the sample needle, the blood sequestration device comprising;

an inlet port configured for receiving the sample of blood;

an outlet port connected with the inlet port and sample needle of blood sampling system; and

a sequestration chamber connected with the inlet port configured for receiving a first amount of the sample of blood, the sequestration chamber having a vent comprising an air permeable blood barrier configured for sequestering at least a first portion of the first amount of the sample of blood;

a sampling channel having a proximal end connected with the inlet port configured for receiving the subsequent portion of the sample of blood,

wherein the sequestration chamber, the sampling channel and the inlet port being configured to allow the subsequent portion of the sample of blood to bypass the sequestration chamber and the first portion of the blood sequestered therein, and direct the subsequent portion of the sample of blood toward the outlet port, wherein the outlet port is connected with a distal end of the sampling channel; and

further comprising a housing that houses and defines the inlet port, the outlet port, the sequestration chamber and the sampling channel.

12. The blood sample optimization system in accordance with claim **11**, wherein the sequestration chamber of the blood sequestration device is at ambient air pressure, and wherein the sequestration chamber receives the first portion of the blood sample by blood pressure of the patient overcoming the ambient air pressure in the sequestration chamber.

13. The blood sample optimization system in accordance with claim **11**, wherein the sample needle includes a seal that is pierced by the evacuated blood collection tube to open access to the patient needle via the blood sampling pathway.

14. The blood sample optimization system in accordance with claim **11**, wherein the air permeable blood barrier of the blood sequestration device includes an air permeable material that seals upon contact with blood.

15. The blood sequestration device in accordance with claim **11**, wherein the sequestration chamber includes a sequestration channel defined in the housing.

16. The blood sample optimization system in accordance with claim **11**, wherein the blood sampling pathway of the blood sampling system comprises tubing.

* * * * *

专利名称(译)	血液样本优化系统和血液污染物隔离装置和方法		
公开(公告)号	US10010282	公开(公告)日	2018-07-03
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[标]申请(专利权)人(译)	该解决方案公司		
申请(专利权)人(译)	该解决方案，公司		
当前申请(专利权)人(译)	KURIN INC.		
[标]发明人	ROGERS BOBBY E KANG GINO DETLOFF JOHN		
发明人	ROGERS, BOBBY E. KANG, GINO DETLOFF, JOHN		
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优先权	62/196797 2015-07-24 US 62/238636 2015-10-07 US 62/318194 2016-04-04 US		
其他公开文献	US20170020428A1		
外部链接	Espacenet		

摘要(译)

描述了血液样品优化系统和方法，其减少或消除收集的血液样品中的污染物，这反过来减少或消除血液培养物中的假阳性读数或收集的血液样品的其他测试。血液样本优化系统可包括位于患者针和样本针之间的血液隔离装置。血液隔离装置可以包括用于隔离初始的，可能被污染的血液等分试样的隔离室，并且还可以包括采样通道，该采样通道绕过隔离室以在初始等分试样之后在患者针和样品针之间传送可能未受污染的血液。血液在隔离室中被隔离。