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NEEDLE WITH CLOSURE AND METHOD

Abstract

A needle has a hollow shaft, a tip formed at one end of the shaft, one or more ports in fluid communication with the interior of the hollow shaft, and a closure. The closure and/or the shaft is movable between (i) a first position wherein the closure closes the port(s), and (ii) a second position opening the port(s).

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Background/Summary

CROSS-REFERENCE TO RELATED APPLICATIONS [0001] This patent application is a divisional application of co-pending U.S. patent application Ser. No. 17/508,812, filed Oct. 22, 2021, issuing as U.S. Pat. No. 12,097,984, which is a continuation of U.S. patent application Ser. No. 13/450,306, filed Apr. 18, 2012, claiming benefit under 35 U.S.C. § 119 (c) to U.S. Provisional Patent Application Ser. No. 61/476,523, filed Apr. 18, 2011, all of which are hereby expressly incorporated by reference in its entirety as part of the present disclosure.

FIELD OF THE INVENTION

[0002] The present invention relates to needles, and more particularly, relates to filling needles and methods of filling with needles.

BACKGROUND INFORMATION

[0003] A typical prior art filling needle includes a hollow stainless steel shaft, a non-coring, conically-pointed tip fixedly secured to the distal end of the shaft, and diametrically opposed fluid ports proximal to the tip and in fluid communication between the interior of the shaft and the ambient atmosphere. One drawback encountered with prior art filling needles is that the interior of the needle, and any fluid contained therein, is exposed to the ambient atmosphere through the open fluid ports. Even though the needle ports or eyes are very small, the incidence of contamination in aseptic filling is such that there still can be a need to control the environment in prior art filling machines in order to protect the filling needles, and particularly the end opening(s) of the filling needles, regardless of type. If the ambient atmosphere is contaminated, the open ports can allow the interior of the needle and any fluid passing therethrough to become contaminated. On the other hand, if the needle is used to dispense a contaminated fluid, or a fluid that might be harmful if it is exposed to or comes into contact with a person, the open ports can allow such fluid to contaminate its ambient atmosphere or potentially harm a person that contacts the needle or is in the vicinity thereof. In prior art filling machines, including the needle filling and laser resealing machines described in the present inventor's U.S. Pat. No. 6,604,561, the regulatory agencies require control of the needle environment in order to protect against any exposure of the product itself to the environment and the resulting contamination of the product that might occur. Accordingly, the surfaces that may come into contact with the product, including the surfaces of the stopper and vial, are protected from the environment until the closed vial is pierced by the sterile needle. But, if for whatever reason, the latter were to be contaminated, a risk of contaminating the product inside the vial would exist.

[0004] It is an object of the present invention to overcome one or more of the above-described drawbacks and/or disadvantages of the prior art, including to reduce the risk of contamination and/or to reduce the controls over, or the need to control a filling needle environment.

SUMMARY OF THE INVENTION

[0005] In accordance with a first aspect, a needle comprises a hollow shaft; a tip formed at one end of the shaft; a port in fluid communication with the interior of the hollow shaft; and a closure. The closure and/or the shaft is movable between (i) a first position wherein the closure closes the port,

and (ii) a second position opening the port. To prevent contamination of the needle from external sources, the closure may be configured to provide a substantially fluid-tight and/or airtight or hermetic seal between the port and ambient atmosphere in the closed position.

[0006] In some embodiments, the closure is biased in the direction from the second position to the first position to normally close the port. In some such embodiments, the needle includes a biasing member, e.g., a spring, biasing the closure in the direction from the second position to the first position.

[0007] In some embodiments, the closure is engageable with a penetrable septum to move the closure and/or the shaft from the first position wherein the closure closes the port, to the second position opening the port, upon penetrating the septum with the needle. In some such embodiments, at least one of the closure and the shaft is movable from the second position wherein the port is opened, to the first position wherein the port is closed, during or upon withdrawing the needle from the septum.

[0008] In some embodiments, the closure extends annularly about the shaft. In some embodiments, the closure includes a flange on one end thereof engageable with a biasing member or spring for biasing the closure in the direction from the second position to the first position. An opposite end of the closure is engageable with a stop surface of the needle to stop the closure in the first position. In some embodiments, a distal end of the closure is substantially flush with an adjacent portion of the needle tip. In some embodiments, the tip is defined by a non-coring, conically-pointed tip.

[0009] In accordance with another aspect, a needle comprises first means for providing a conduit for the passage of fluid therethrough; second means formed at one end of the first means for penetrating a septum; third means in fluid communication with the conduit for passage of fluid from the conduit therethrough; and fourth means for closing the third means. The fourth means and/or the first means is movable between (i) a first position wherein the fourth means closes the third means, and (ii) a second position opening the third means. In some embodiments, the first means is a needle shaft, the second means is a needle tip, the third means is a port, and the fourth means is a closure.

[0010] In accordance with another aspect, a method comprising the following steps: [0011] (i) piercing a septum with a needle and placing the needle in fluid communication with a chamber; [0012] (ii) during or after the piercing step, moving a closure and/or a filling port of the needle from a closed position closing the filling port to an open position opening the filling port; and [0013] (iii) introducing fluid from the needle into the chamber after full perforation of the septum and/or after the needle port(s) or eye(s) have passed through the interior surface of the septum and are located within the chamber.

[0014] In accordance with another aspect, the method further comprises the following steps: [0015] (iv) withdrawing the needle from the septum; and [0016] (v) before and/or during the withdrawing step, moving the closure and/or the filling port of the needle from the open position to the closed position.

[0017] Some embodiments further comprise substantially sealing the filling port from ambient atmosphere in the closed position. Some embodiments further comprise substantially preventing any contact between the filling port and the septum during the penetrating and withdrawing steps. Some such embodiments further comprise interposing the closure between the filling port and septum to substantially prevent any contact between the filling port and septum.

[0018] Some embodiments further comprise the step of sealing the resulting penetration aperture in the septum. In these embodiments the self-closing properties of the septum material are engineered in a manner known to those of ordinary skill in the pertinent art based on the teachings herein to prevent any opening or passage between the needle and the pierced septum material, or any passage between the interior of the filling machine and the sterile chamber of the container or device to be filled after the septum is pierced. One objective and/or advantage of such embodiments is to demonstrate that the sterile container is always closed from its ambient environment even when

mechanically opened by the filling needle so that after piercing and withdrawal of the needle, the visco-clastic or self-closing properties of the septum are such that any opening in the residual penetration aperture would be less than or equal to about 0.05 micrometer, such as less than or equal to about 0.02 micrometer, or even less than or equal to about 0.01 micrometer, or otherwise at a size that prevents fluid, including air, from penetrating through the resulting penetration aperture, prior to rescaling thereof. In some such embodiments, the scaling step includes applying radiation or energy to the septum. In some embodiments, the scaling step includes at least one of thermal sealing, laser sealing and liquid sealant scaling. An exemplary liquid sealant is silicone. In some such embodiments, the liquid silicone is over-molded onto a compatible septum and/or cap material to ensure seal integrity and durability and enhance safety standards.

[0019] Some embodiments further comprise performing the penetrating, filling and withdrawing steps in a non-sterile or relatively low sterility assurance level (“SAL”) environment, such as about log 3 or lower, including about log 2 or about log 1; filling a sterile fluid through the needle and into the chamber; and maintaining the sterility of the filled fluid throughout the penetrating, filling and withdrawing steps. Some embodiments further comprise scaling a resulting penetration aperture in the septum and maintaining the sterility of the filled fluid during the scaling step.

[0020] One advantage of the present invention is that the closure closes the needle port(s) with respect to ambient atmosphere thereby preventing contamination of the needle port and interior of the needle and, in turn, preventing contamination of fluid flowing therethrough. Another advantage of certain embodiments is that they allow sterile filling within a non-aseptic, non-sterile or relatively low SAL environment (e.g., about log 3 or lower) while nevertheless sterile filling fluids into containers or devices and hermetically rescaling them. Accordingly, the filling of a non-preserved or preservative-free formulation with a self-closing filling needle of the present invention without control of the filling needle environment, or with reduced needle environment controls, can be safer than filling a preserved formulation in an aseptically-controlled environment with prior art filling apparatus and methods. Yet another advantage of some embodiments is that the closure is interposed between the needle port and a septum to prevent contact between the needle port and septum, and thereby further prevent any contamination of the needle port and interior of the needle and of any fluid flowing therethrough. In some embodiments, the combination of the self-closing needle, such as the needle with “sliding shutter” closure, and a liquid silicone drop (“LSD”) or other resealable septum, creates a unique system and method allowing for the reduction or elimination of environmental controls required by prior art sterile filling systems and methods, thereby allowing for a simplification in equipment, a reduction in the time associated with setup and operation of the equipment, and/or a reduction in the cost of equipment and/or aseptic filling and processing. As a consequence, devices and methods of the invention facilitate the ability of manufacturers of any size, including small entity manufacturers, to safely fill preserved or preservative-free formulations into aseptic environments, and to do so at a lower cost, with improved efficiency and/or in less time, than required by prior art aseptic filling devices and methods.

[0021] Other objects and advantages of the present invention, and/or of the currently preferred embodiments thereof, will become more readily apparent in view of the following detailed description and the accompanying drawings.

Description

BRIEF DESCRIPTION OF THE DRAWINGS

[0022] FIG. 1 is a sequential, cross-sectional view of a needle showing the separate components of the needle, and the assembly thereof; and

[0023] FIGS. 2A through 2E are sequential cross-sectional views of the needle of FIG. 1 showing

the needle during penetration of and withdrawal from a rescalable septum for filling a device or chamber of a device through such resealable septum.

DETAILED DESCRIPTION OF EMBODIMENTS OF THE INVENTION

[0024] In FIGS. 1 and 2, a needle is indicated generally by the reference numeral **10**. The needle **10** comprises a hollow shaft **12**, a tip **14** formed at one end of the shaft; two ports **16**, **16** in fluid communication with the interior of the hollow shaft **12**, and a closure **18**. In the illustrated embodiments, the two ports **16** are diametrically opposed relative to each other; however, as may be recognized by those of ordinary skill in the pertinent art based on the teachings herein, the needle may define any number of ports that may define any of numerous different configurations and locations. The closure **18** and/or the shaft **12** is movable between (i) a first position wherein the closure closes the ports **16**, as shown typically in FIG. 1, and (ii) a second position opening the ports **16**, as shown typically in FIG. 2C. In the illustrated embodiment, when in the closed position, the closure **18** forms a substantially fluid-tight seal between the ports **16** and ambient atmosphere. The closure **18** is biased in the direction from the second or open position to the first or closed position to normally close the ports **16**. In the illustrated embodiment, the needle **10** includes a coil spring **20** that biases the closure in the direction from the second or open position to the first or closed position. As may be recognized by those of ordinary skill in the pertinent art based on the teachings herein, the closure may be biased in any of numerous different ways that are currently known or that later become known, using biasing members other than springs, and if a spring is used, any of numerous different springs or combinations of springs may be used. In the illustrated embodiment, the closure **18** is an axially or vertically sliding “shutter” closure that slides axially over the needle shaft **12** between the normally closed and open positions. However, as may be recognized by those of ordinary skill in the pertinent art based on the teachings herein, the closure may take any of numerous different configurations that are currently known, or that later become known, for performing the function of the closure as described herein.

[0025] The closure **18** extends both annularly and axially about the shaft **12** and is slidably mounted on the shaft. The closure **18** includes an annular flange **22** on one end thereof that is engageable with the spring **20** for biasing the closure in the direction from the second or open position to the first or closed position. An opposite end **24** of the closure **18** is engageable with an annular stop surface **26** of the needle tip to stop the closure in the first or closed position. The distal end **24** and substantially cylindrical body of the closure **18** are substantially flush with the perimeter of the stop surface **26** and adjacent portion of the needle tip **14**. The annular flange **22**, on the other hand, projects radially outwardly to provide a surface for seating and engaging the distal end of the spring **20**. In the illustrated embodiment, the needle tip **14** is defined by a non-coring, conically-pointed tip; however, as may be recognized by those of ordinary skill in the pertinent art based on the teachings herein, the needle tip may define any of numerous other needle tip configurations that are currently known, or that later become known, such as a trocar tip. In one configuration, the spring force of the spring **20** is sufficient to allow the needle to penetrate the septum while maintaining the closure **18** in the closed position during penetration of the closure through the septum and until the annular flange **22** of the closure engages an exterior surface of the septum (or other exterior or stop surface of the device) to cause relative movement of the closure and shaft against the bias of the spring from the normally closed position to the open position and, in turn, expose the sterile needle ports to the sterile device chamber.

[0026] An axially-elongated flange **28** includes bosses **30** that are received within corresponding apertures **32** formed in the needle shaft **12** to fixedly secure the flange to the shaft. A needle holder **34** is secured to the flange **28** and includes a barbed fitting **36** for attachment to a filling line (not shown). In the illustrated embodiment, the flange **28** is over-molded to the end of the shaft **12**, and the needle holder **34** is over-molded to the flange **28**. The coil spring **20** is mounted between the distal end of the axially-elongated flange **28** and the closure annular flange **22**. As may be recognized by those of ordinary skill in the pertinent art based on the teachings herein, any of

numerous different types of fittings or connections that are currently known, or that later become known, equally may be employed for connecting the needle to a filling or other type of line or conduit.

[0027] As shown typically in FIG. 2, the needle **10** may be used to aseptically or sterile fill fluids through a penetrable septum **38** into a chamber **40** of a container or other device (not shown). As shown in FIG. 2A, prior to penetrating the septum **38**, and when the needle tip **14** is exposed to the ambient atmosphere, the closure **18** is in the closed position sealing the ports **16** with respect to ambient atmosphere to thereby maintain the sterility of the ports and of the interior of the needle. As shown in FIG. 2B, upon penetrating the septum **38**, the closure **18** is interposed between the ports **16** and the septum **38** to substantially prevent contact between the ports and the septum. Then, as shown in FIG. 2C, when the ports **16** are located within the chamber **40**, the annular flange **22** of the closure engages the septum, and/or the frictional engagement between the cylindrical body of the closure **18** and the septum **38**, prevents further movement of the closure relative to the septum. Further penetration of the needle **10** into the septum **38** causes the shaft **12** and needle tip **14** to move relative to the closure **18** against the bias of the spring **20** to, in turn, move the ports **16** to the open position. In the open position of FIG. 2C, the fluid within the needle is permitted to flow through the open ports **16** and into the chamber **40**. Since the sterile ports **16** are not exposed to the ambient atmosphere, the ports, interior of the needle, and fluid flowing therethrough, are not contaminated and/or are maintained sterile as the fluid is injected or otherwise dispensed into the chamber **40**. After the chamber **40** is filled as desired, and as shown typically in FIG. 2D, the needle **10** is withdrawn from the septum **38**. As the needle is withdrawn, the spring **20** biases the closure **18** downwardly or in the direction of the septum **38**. Therefore, as the needle shaft **12** is withdrawn, it is moved axially relative to the closure **18** to, in turn, move the ports **16** into the closed position behind the closure. The sliding shutter or closure **18** may be configured to substantially prevent contact between the needle eyes or ports **16**, and the sliding shutter or closure is closed over the needle eyes or ports prior to their passage through the septum and/or withdrawal therefrom. When the end **24** of the closure **18** engages the stop surface **26** of the needle tip, the closure is fixed in the closed position, and is maintained in the closed position by the downward force or bias of the spring **20**. Thus, during and upon, and/or before, withdrawal of the needle **10** from the septum **38**, the closure **18** closes the ports **16** and prevents any contamination of the ports or interior of the needle. In some embodiments, the septum **38** is engineered to self-close and thereby ensure that the head loss left by the residual needle aperture **42** after the tip of the needle is withdrawn prevents any fluid ingress therethrough.

[0028] As shown typically in FIG. 2E, although the septum may be self-closing as described above, the resulting needle or penetration aperture **42** in the septum may be resealed by a further process. Such processes include mechanically (such as by an overlying cover (not shown)), by applying radiation or energy to the septum, e.g., thermal rescaling, by laser rescaling, or by applying a liquid sealant thereto, which may be cured at room temperature or by applying radiation or energy to the sealant, such as a silicone or silicon-based sealant, e.g., UV (ultraviolet) or visible light curable composition, to form a fluid tight or hermetic seal and thereby maintain the sterility of the filled fluid in the chamber. Examples of resealable septums and processes for rescaling them are described, for example, in the following patents and applications that are incorporated by reference in their entirety herein: U.S. patent application Ser. No. 08/424,932, filed Apr. 19, 1995, entitled "Process for Filling a Sealed Receptacle under Aseptic Conditions," issued as U.S. Pat. No. 5,641,004; U.S. patent application Ser. No. 09/781,846, filed Feb. 12, 2001, entitled "Medicament Vial Having a Heat-Scalable Cap, and Apparatus and Method for Filling Vial," issued as U.S. Pat. No. 6,604,561, which, in turn, claims priority from U.S. Provisional Patent Application Ser. No. 60/182,139, filed Feb. 11, 2000, entitled "Heat-Scalable Cap for Medicament Vial;" U.S. patent application Ser. No. 10/655,455, filed Sep. 3, 2003, entitled "Sealed Containers and Methods of Making and Filling Same," issued as U.S. Pat. No. 7,100,646, which, in turn, claims priority from

similarly titled U.S. Provisional Patent Application Ser. No. 60/408,068, filed Sep. 3, 2002; U.S. patent application Ser. No. 10/766,172, filed Jan. 28, 2004, entitled “Medicament Vial Having a Heat-Scalable Cap, and Apparatus and Method for Filling the Vial,” issued as U.S. Pat. No. 7,032,631, which, in turn claims priority from similarly titled U.S. Provisional Patent Application Ser. No. 60/443,526, filed Jan. 28, 2003 and similarly titled U.S. Provisional Patent Application Ser. No. 60/484,204, filed Jun. 30, 2003; U.S. Provisional Patent Application entitled “Modular Filling Apparatus and Method,” filed Apr. 13, 2012; U.S. patent application Ser. No. 12/901,420, entitled “Device with Co-Molded Closure, One-Way Valve and Variable Volume Storage Chamber and Related Method,” filed Oct. 8, 2010, which, in turn, claims priority to similarly titled U.S. Provisional Patent Application Ser. No. 61/250,363, filed Oct. 9, 2009. The process then may be repeated whereby the same needle **10** may be used to aseptically or sterile fill plural or numerous chambers of devices.

[0029] When filling a sterile product, the self-closing septum **38** prevents the filled product from being contaminated by the device environment. In other applications, the self-closing septum prevents the product itself from contaminating its environment. For example, some products, such as cytotoxic products for treating cancer, or radioactive products, are hazardous and/or can be dangerous to operators, treatment professionals or other persons that might need to handle the filling machine or filled devices. Prior art equipment for handling such dangerous substances can be complex and costly. One advantage of the self-closing needle technology of the present invention is that it allows such dangerous or hazardous products to be filled and handled in a relatively safe and less costly manner than encountered in the prior art.

[0030] In another embodiment, the filling machine includes a first needle for piercing the septum (not shown), and a second self-closing needle for piercing the septum through the resulting penetration aperture formed by the first needle. In this embodiment, the first needle may be a solid needle without any lumen or closure, and may define a different diameter than the second needle, such as a smaller diameter. The first needle may be located in a first station and the second needle may be located in a second station, wherein the devices with septums are transported from the first station to the second station on a motorized conveyor. Each station may include an over pressure of sterile air or other gas. Alternatively, the first and second needles may be located in the same station on a common manifold or fixture to reduce the system footprint and/or to facilitate alignment of the second needle with the penetration aperture of the first needle. As described above, the septum is formed of a visco-clastic material that self-closes after withdrawal of each needle therefrom, and therefore prevents any contamination of the interior of the device between the first and second needle penetrations, and between the second needle penetration and resealing of the resulting penetration aperture. One advantage of this embodiment is that the penetration aperture formed by the first needle reduces that frictional force encountered by the second needle and closure during passage through the septum, and therefore reduces the spring force required to maintain the closure in the normally closed position during septum penetration.

[0031] As may be recognized by those of ordinary skill in the pertinent art based on the teachings herein, numerous changes and modifications may be made to the above-described and other embodiments of the present invention without departing from its scope as defined in the appended claims. For example, the needle, closure, spring of biasing member and holder may be made of any of numerous different metals or plastics that are currently known or that later become known. The term “needle” is used herein to mean any of numerous different types of devices that are used to penetrate and introduce matter into, or withdraw matter from, an object, such as a chamber or device, that are currently known, or that later become known. The term “septum” is used herein to mean any of numerous different types of needle penetrable septums, stoppers or other devices that are penetrable by a needle for filling a chamber therethrough. The needles may be used in sterile or non-sterile environments, to needle fill with or in accordance with any of numerous different filling

devices or methods that are currently known, or that later become known. Accordingly, this detailed description of embodiments is to be taken in an illustrative, as opposed to a limiting sense.

Claims

1. A transfer system comprising: a device defining a chamber therein adapted to receive fluid therein and having an opening, and a pierceable septum in fluid communication with the chamber and sealing said opening; and a needle comprising a hollow shaft; a septum-piercing tip formed at a distal end of the shaft; at least one port in fluid communication with the interior of the hollow shaft; and a closure; wherein the needle is adapted to pierce the septum; wherein one or more of the closure or the shaft is movable between (i) a first position wherein the closure closes the at least one port to prevent passage of fluid through the at least one port and hermetically seal the at least one port with respect to ambient atmosphere, and (ii) a second position opening the at least one port to permit passage of fluid through the at least one port; wherein, along an entire length of the at least one port and in the first position, the needle defines a straight outermost surface thereof; and wherein (a) the closure is biased in a direction from the second position toward the first position to normally close the at least one port, and (b) when the closure is located in its most distal position relative to the shaft, one or more of (i) at least a portion of the tip is exposed to ambient atmosphere or (ii) the closure does not enclose at least a portion of the tip.

2-5. (canceled)

6. A system as defined in claim 1, wherein the closure includes a flange or projection engageable with a biasing member for biasing the closure in a direction from the second position toward the first position.

7. A system as defined in claim 6, wherein an end of the closure is engageable with a stop surface of the to stop the closure in the first position.

8-12. (canceled)

13. A system as defined in claim 1 adapted so that a portion of the closure extending along the at least one port in the first position is adapted to at least partially penetrate into or through the septum in the first position.

14. A system as defined in claim 1, wherein a portion of the closure radially adjacent to the port is adapted to at least partially penetrate into or through the septum in the first position.

15. A system as defined in claim 14, wherein a diameter of the closure at a distal end thereof is no greater than a maximum diameter of the tip.

16. A system as defined in claim 1, wherein the shaft defines a proximal end and a distal end, and the closure defines a surface located, in the first position, closer to the proximal end of the shaft than the portion of the port closest to the distal end of the shaft and adapted to engage the septum and thereby one or more of (a) cause relative movement of the closure and the shaft, or (b) prevent further movement of the closure relative to the septum.

17. (canceled)

18. A system as defined in claim 16, wherein the surface is axially spaced from a distal end of the at least one port a distance at least equal to a thickness of the septum to be pierced by the needle.

19. A transfer system comprising: a device defining a chamber therein adapted to receive fluid therein and having an opening, and a pierceable septum in fluid communication with the chamber and sealing said opening; and a needle comprising first means for providing a conduit for the passage of fluid therethrough; second means formed at one end of the first means for piercing the septum; third means in fluid communication with the conduit for passage of fluid therethrough; fourth means for closing the third means, wherein one or more of the fourth means or the first means is movable between (i) a first position wherein the fourth means closes and hermetically seals the third means with respect to ambient atmosphere and prevents passage of fluid through the third means and (ii) a second position opening the third means to permit passage of fluid through

the third means; and fifth means for biasing the fourth means in a direction from the second position toward the first position to normally close the third means; wherein the needle is adapted to pierce the septum; wherein, along an entire length of the third means and in the first position, the needle defines a straight outermost surface thereof; and wherein, when the fourth means is located in its most distal position relative to the first means, one or more of (i) at least a portion of the second means is exposed to ambient atmosphere or (ii) the fourth means does not enclose at least a portion of the second means.

20. (canceled)

21. A method comprising the following steps: transferring fluid between a device and a needle of a transfer system, wherein the device defines a chamber therein adapted to receive fluid therein and having an opening, and a pierceable septum in fluid communication with the chamber and sealing said opening, the transferring step including: piercing the septum with a needle adapted to pierce the septum and placing the needle in fluid communication with the chamber, the needle comprising a hollow shaft; a septum-piercing tip formed at a distal end of the shaft; at least one port in fluid communication with the interior of the hollow shaft; and a closure; wherein one or more of the closure or the shaft is movable between (i) a first position wherein, along an entire length of the at least one port, the needle defines a straight outermost surface thereof, and the closure closes the at least one port to prevent passage of fluid through the at least one port and hermetically seal the at least one port with respect to ambient atmosphere, and (ii) a second position opening the at least one port to permit passage of fluid through the at least one port; and wherein (a) the closure is biased in a direction from the second position toward the first position to normally close the at least one port, and (b) when the closure is located in its most distal position relative to the shaft, one or more of (i) at least a portion of the tip is exposed to ambient atmosphere or (ii) the closure does not enclose at least a portion of the tip; after or during the piercing step, moving one or more of the closure or the shaft of the needle from the first position to the second position; and flowing fluid between the needle and the chamber.

22. A method as defined in claim 21, further comprising the following steps: withdrawing the needle from the septum; and before or during the withdrawing step, moving one or more of the closure or the shaft of the needle from the second position to the first position.

23-35. (canceled)

36. A method as defined in claim 21, further comprising, while the closure is in the first position, penetrating a portion of the closure extending along the at least one port in the first position at least partially into or through the septum.

37-39. (canceled)

40. A transfer system comprising: a device defining a chamber therein adapted to receive fluid therein and having an opening, and a pierceable septum in fluid communication with the chamber and sealing said opening; and a needle comprising a hollow shaft; a septum-piercing tip formed at one end of the shaft; at least one port in fluid communication with the interior of the hollow shaft; and a closure; wherein the needle is adapted to pierce the septum; wherein one or more of the closure or the shaft is movable between (i) a first position wherein the closure closes the at least one port to prevent passage of fluid through the at least one port and hermetically seal the at least one port with respect to ambient atmosphere, and (ii) a second position opening the at least one port to permit passage of fluid through the at least one port; and wherein a portion of the closure radially adjacent to the port is adapted to at least partially penetrate into or through the septum in the first position.

41-43. (canceled)

44. A system as defined in claim 40 adapted so that a portion of the closure extending along the at least one port in the first position is adapted to at least partially penetrate into or through the septum in the first position.

45. A transfer system comprising: a device defining a chamber therein adapted to receive fluid

therein and having an opening, and a pierceable septum in fluid communication with the chamber and sealing said opening; and a needle comprising a hollow shaft defining a proximal end and a distal end; a septum-piercing tip formed at the distal end of the shaft; at least one port in fluid communication with the interior of the hollow shaft; and a closure; wherein the needle is adapted to pierce the septum; wherein one or more of the closure or the shaft is movable between (i) a first position wherein the closure closes the at least one port to prevent passage of fluid through the at least one port and hermetically seal the at least one port with respect to ambient atmosphere, and (ii) a second position opening the at least one port to permit passage of fluid through the at least one port; and wherein the closure defines a surface located, in the first position, closer to the proximal end of the shaft than the portion of the port closest to the distal end of the shaft and adapted to engage the septum and thereby one or more of (a) cause relative movement of the closure and the shaft, or (b) prevent further movement of the closure relative to the septum.

46. A system as defined in claim 45 wherein the surface is spaced from a distal end of the at least one port a distance at least equal to a thickness of the septum to be pierced by the needle.

47. An apparatus comprising: a first device comprising a hollow shaft; at least one port in fluid communication with an interior of the hollow shaft; and a closure; wherein one or more of the closure or the shaft is movable between (i) a first position wherein the closure closes the at least one port to prevent passage of fluid through the at least one port and hermetically seal the at least one port with respect to ambient atmosphere, and (ii) a second position opening the at least one port to permit passage of fluid through the at least one port; and a second device adapted to engage with the first device for fluid flow therebetween, and including a septum having an aperture therethrough configured to receive at least a portion of the shaft and the closure during engagement of the first device and the second device; wherein the closure is adapted to at least partially penetrate into or through the aperture in the first position.

48. (canceled)

49. An apparatus as defined in claim 47 adapted so that one or more of (i) a portion of the closure extending along the at least one port in the first position is adapted to at least partially penetrate into or through the aperture in the first position; (ii) during at least a portion of said at least partial penetration of the closure into or through the aperture, the at least one port is prevented from contacting the septum; or (iii) during at least a portion of said at least partial penetration of the closure into or through the aperture, the closure is interposed between the at least one port and the septum.

50. A method comprising: engaging a first device and a second device, the first device comprising a hollow shaft; at least one port in fluid communication with an interior of the hollow shaft; and a closure; wherein one or more of the closure or the shaft is movable between (i) a first position wherein the closure closes the at least one port to prevent passage of fluid through the at least one port and hermetically seal the at least one port with respect to ambient atmosphere, and (ii) a second position opening the at least one port to permit passage of fluid through the at least one port; and the second device comprising a septum having an aperture therethrough configured to receive at least a portion of the shaft and the closure during said engaging of the first device and the second device; wherein the closure is adapted to at least partially penetrate into or through the aperture in the first position; penetrating the shaft and closure at least partially into or through the aperture; during or after the penetrating step, moving one or more of the closure or the shaft from the first position to the second position; and flowing fluid between the first device and the second device; wherein the penetrating step includes at least partially penetrating the closure into or through the aperture with the closure in the first position.

51. (canceled)

52. A method as defined in claim 50, wherein the penetrating step includes one or more of (i) while the closure is in the first position, at least partially penetrating a portion of the closure extending along the at least one port in the first position into or through the aperture; (ii) substantially

preventing any contact between the at least one port and the septum; or (iii) interposing the closure between the at least one port and septum.

53. (canceled)
