NEEDLE WITH CLOSURE AND METHOD

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This patent application claims the benefit under 35 U.S.C. § 119(e) to U.S. Provisional Patent Application Serial No. 61/476,523, entitled "Filling Needle and Method," filed April 18, 2011, which is 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. Patent 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:

(i) piercing a septum with a needle and placing the needle in fluid communication with a chamber;

(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

(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.

[0011] In accordance with another aspect, the method further comprises the following steps:

(iv) withdrawing the needle from the septum; and

(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.

[0012] 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.

[0013] 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-elastic 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 resealing thereof. In some such embodiments, the sealing step includes applying radiation or energy to the septum. In some embodiments, the sealing step includes at least one of thermal sealing, laser sealing and liquid sealant sealing. 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.

[0014] 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 sealing a resulting penetration aperture in the septum and maintaining the sterility of the filled fluid during the sealing step.

[0015] 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 resealing 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.

[0016] 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.

BRIEF DESCRIPTION OF THE DRAWINGS

[0017] FIG. 1 is a sequential, cross-sectional view of a needle showing the separate components of the needle, and the assembly thereof; and

[0018] 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 resealable septum for filling a device or chamber of a device through such resealable septum.

DETAILED DESCRIPTION OF EMBODIMENTS OF THE INVENTION

[0019] 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.

[0020] 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.

[0021] 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.

[0022] 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.

[0023] 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 resealing, by laser resealing, 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 resealing them are described, for example, in the following patents and applications that are incorporated by reference in their entirety herein: U.S. Patent Application Serial No. 08/424,932, filed April 19, 1995, entitled "Process for Filling a Sealed Receptacle under Aseptic Conditions," issued as U.S. Patent No. 5,641,004; U.S. Patent Application Serial No. 09/781,846, filed February 12, 2001, entitled "Medicament Vial Having a Heat-Sealable Cap, and Apparatus and Method for Filling Vial," issued as U.S. Patent No. 6,604,561, which, in turn, claims priority from U.S. Provisional Patent Application Serial No. 60/182,139, filed February 11, 2000, entitled "Heat-Sealable Cap for Medicament Vial;" US. Patent Application Serial No. 10/655,455, filed September 3, 2003, entitled "Sealed Containers and Methods of Making and

Filling Same," issued as U.S. Patent No. 7,100,646, which, in turn, claims priority from similarly titled U.S. Provisional Patent Application Serial No 60/408,068, filed September 3, 2002; U.S. Patent Application Serial No. 10/766,172, filed January 28, 2004, entitled "Medicament Vial Having a Heat-Sealable Cap, and Apparatus and Method for Filling the Vial," issued as U.S. Patent No. 7,032,631, which, in turn claims priority from similarly titled U.S. Provisional Patent Application Serial No. 60/443,526, filed January 28, 2003 and similarly titled U.S. Provisional Patent Application Serial No. 60/484,204, filed June 30, 2003; U.S. Provisional Patent Application entitled "Modular Filling Apparatus and Method," filed April 13, 2012; U.S. Patent Application Serial No. 12/901,420, entitled "Device with Co-Molded Closure, One-Way Valve and Variable Volume Storage Chamber and Related Method," filed October 8, 2010, which, in turn, claims priority to similarly titled U.S. Provisional Patent Application Serial No. 61/250,363, filed October 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.

[0024] 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.

[0025] 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-elastic 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.

[0026] 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.

What is claimed is:

1. A needle comprising: a hollow shaft; a 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 at least one of the closure and the shaft is movable between (i) a first position wherein the closure closes the at least one port, and (ii) a second position opening the at least one port.

2. A needle as defined in claim 1, wherein in the first position, the closure forms a substantially fluid-tight seal between the at least one at least one port and ambient atmosphere.

3. A needle as defined in claim 1 or 2, wherein the closure is biased in the direction from the second position toward the first position to normally close the at least one port.

4. A needle as defined in claim 3, further including a biasing member biasing the closure in the direction from the second position to the first position.

5. A needle as defined in any of the preceding claims, wherein the closure is engageable with a penetrable septum to move at least one of the closure and the shaft from the first position wherein the closure closes the at least one port, to the second position opening the at least one port, upon penetrating the septum with the needle.

6. A needle as defined in claim 5, wherein at least one of the closure and the shaft is movable from the second position wherein the at least one port is opened, to the first position wherein the at least one port is closed, during or upon withdrawing the needle from the septum.

7. A needle as defined in any of the preceding claims, wherein the closure extends annularly about the shaft.

8. A needle as defined in any of the preceding claims, wherein the closure includes a flange on one end thereof engageable with a biasing member for biasing the closure in the direction from the second position to the first position.

9. A needle as defined in claim 8, wherein an end of the closure opposite the flange is engageable with a stop surface of the needle to stop the closure in the first position.

10. A needle as defined in any of the preceding claims, wherein a distal end of the closure is substantially flush with an adjacent portion of the needle tip.

11. A needle as defined in any of the preceding claims, wherein the tip is defined by a non-coring, conically-pointed tip.

12. A needle as defined in any of the preceding claims, further comprising a holder connected to an end of the shaft opposite the tip and engageable in fluid communication with a filling line for introducing fluid from the filling line through the needle.

13. A needle as defined in any of the preceding claims, wherein the holder is over-molded to the shaft.

14. 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 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, wherein at least one of the fourth means and 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.

15. A needle as defined in claim 14, wherein the first means comprises a needle shaft, the second means comprises a needle tip, the third means comprises at least one port, and the fourth means comprises a closure.

16. A method comprising the following steps:

piercing a septum with a needle and placing the needle in fluid communication with a chamber;

prior to or during the piercing step, moving at least one of a closure and at least one filling port of the needle from a closed position closing the at least one filling port to an open position opening the at least one filling port; and

introducing fluid from the needle into the chamber.

17. A method as defined in claim 16, further comprising the following steps:

withdrawing the needle from the septum; and

before or during the withdrawing step, moving at least one of the closure and the at least one filling port of the needle from the open position to the closed position.

18. A method as defined in claim 16 or 17, wherein the fluid is introduced from the needle into the chamber after full perforation of the septum or after part of the at least one filling port has passed through an interior surface of the septum and is located within the chamber.

19. A method as defined as defined in claim 18, wherein the fluid is introduced from the needle into the chamber after the at least one filling port is substantially completely located within the chamber.

20. A method as defined in any of claims 17 to 19, further comprising substantially sealing the at least one filling port from ambient atmosphere in the closed position.

21. A method as defined in any of claims 17 to 20, wherein during the penetrating and withdrawing steps, substantially preventing any contact between the at least one filling port and the septum.

22. A method as defined in claim 21, further comprising interposing the closure between the at least one filling port and septum to substantially prevent any contact between the at least one filling port and septum.

23. A method as defined in any of claims 17 to 22, further comprising the step of sealing a resulting penetration aperture in the septum.

24. A method as defined in claim 23, wherein the sealing step includes applying radiation or energy to the septum, thereby sealing the penetration aperture.

25. A method as defined in claims 23 or 24, wherein the sealing step includes at least one of thermal sealing, laser sealing and liquid sealant sealing.

26. A method as defined in claim 25, wherein the liquid sealant is silicone.

27. A method as defined in any of claims 17 to 26, further comprising performing the penetrating, filling and withdrawing steps in a non-sterile environment or an environment

defining a SAL of about log 3 or less; 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.

28. A method as defined in claim 27, further comprising sealing a resulting penetration aperture in the septum and maintaining the sterility of the filled fluid during the sealing step.

29. A method as defined in any of claims 17 to 28, further comprising piercing the septum with a first needle and withdrawing the first needle to create a resulting penetration aperture within the septum, and then performing said piercing step with said needle including the closure through the penetration aperture formed by the first needle.

30. A method as defined in claim 29, wherein the septum is self-closing and substantially prevents the ingress of fluid through the resulting penetration aperture.

31. A method as defined in any of claims 16 to 30, wherein the needle comprises the needle of any one of claims 1 to 13.