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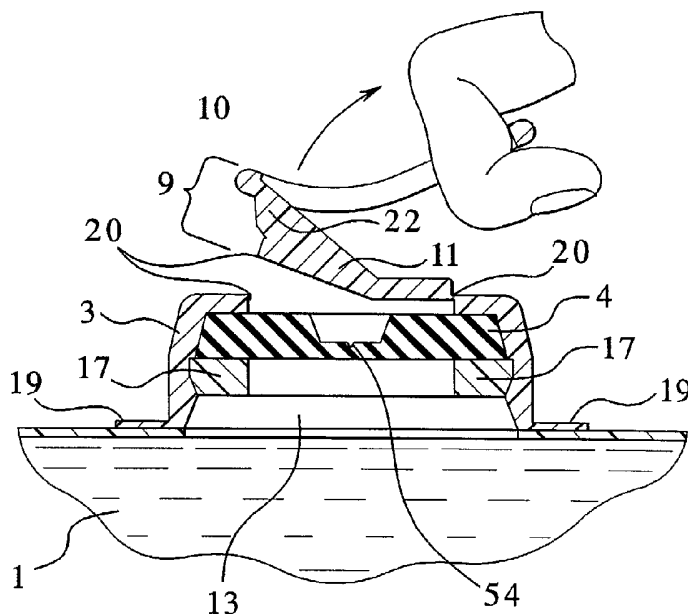
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(54) Title: A PORT, A CONTAINER AND A METHOD FOR ACCESSING A PORT



(57) Abstract: A port, a container and a method for accessing a port for injecting or withdrawing a liquid from the container are provided. The port may allow for the administration of, for example, a drug, to a patient and may be located on the container. The port has a septum having a target area. The port also has a support ring in contact with the septum. A cap is provided to protect the septum. The cap has a ring handle and allows for removal and exposure of the target area of the septum. A needle, for example, may be used to penetrate the septum allowing the addition or withdrawal of a liquid or other drug to or from the container.



WO 03/105748 A1



For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

SPECIFICATION

TITLE OF THE INVENTION

“A PORT, A CONTAINER AND A METHOD FOR ACCESSING A PORT”

BACKGROUND OF THE INVENTION

5 The present invention generally relates to a medication port, an apparatus and a method for using a medication port for injecting or withdrawing a liquid from a container. More specifically, the present invention relates to a method for the injection or withdrawal of a liquid from a container via a medication port. Additionally, the present invention provides an apparatus and a method that may be used for the
10 intravenous administration of a drug.

 It is generally known that an individual may require a form of medication. Often, the medication must be administered to the patient intravenously. For example, it may be impractical or impossible to administer medication to the patient when the patient is unconscious. Additionally, administration of the medication to the patient
15 orally may also be difficult in some cases. Further, the patient may require prolonged, constant and/or immediate medication which may only be administered intravenously. Of course, numerous other reasons exist for providing medication to a patient intravenously.

 Liquids are often stored in containers constructed from, for example, flexible
20 plastic or glass, and often contain a solution of saline, dextrose or lactated Ringer's, for example. An intravenous (IV) fluid drip generally connects an administration port located on the container with an artery in the patient. The mixed solution then flows from the administration port, through the IV, and to the bloodstream of the patient.

 Further, it is generally known to provide a medication port to inject or
25 withdraw a liquid from a container. For example, it is known to provide a medication port on the container through which a drug and/or other solutions may be administered. A needle or cannula is generally implemented to pierce a septum or membrane within the medication port of the container.

 Known medication ports are often constructed as one-way valves which allow
30 the addition of a medication to a container. However, known medication ports are often difficult to maintain in a sterile condition and, therefore, may be unsafe.

Bacteria, viruses and/or other harmful substances, for example, dirt, may be present on the surface of the septum, membrane or container. As a result, such substances may be inadvertently introduced into the solution.

Typically, a medication port is constructed or attached to a container either as
5 an up-port or as a side-port. The up-port is generally located at a distal end of the container while the side port is located on a sidewall of the container.

It is also generally known to provide a septum, also referred to as a bung, within an opening or port of the container. The septum prevents liquid inside of the container from leaving the container. Additionally, the septum reduces the risk of
10 foreign substances from entering the container. Further, known septums often may be pierced by a needle or other object to establish fluid communication with the liquid in the container.

A cap is often incorporated with the port to enclose a septum. However, caps often completely surround the entire opening to the container. As a result, known caps
15 are often bulky, expensive and inefficient. For instance, larger caps require more material in production and add weight and/or complexity to the entire apparatus.

A need, therefore, exists for a medication port as well as an apparatus and a method for injecting or withdrawing a liquid from a container to overcome deficiencies of known ports and apparatus and methods using such a port.
20 Additionally, a need exists for a medication port which allows a liquid to be introduced to a container in a sterile environment.

SUMMARY OF THE INVENTION

The present invention provides a medication port, an apparatus and a method for using a medication port for injecting or withdrawing a liquid from a container. The
25 container may include a solution to be administered to the patient. Additionally, the present invention provides for the injection or withdrawal of a liquid from a container via a medication port in an efficient and sterile manner. More specifically, the present invention may be used for the intravenous administration of a drug. The present invention also provides for a container with a medication port for injecting or
30 withdrawing a liquid from a container.

To this end, in an embodiment of the present invention, an apparatus for injecting or withdrawing a liquid from a container is provided. The port has a housing having an interior defined by peripheral walls extending between a first end and a second end. The port has a septum within the interior at the first end of the housing.

5 The port further has a cap on the first end of the peripheral walls of the housing wherein the cap encloses the first end of the housing and covers the septum. A line of separation is provided between the cap and the peripheral walls of the housing.

In an embodiment, the port has a lip extending between the peripheral walls and the cap at the first end of the housing.

10 In an embodiment, the port has a recess formed in the septum wherein the recess includes a slit.

In an embodiment, the port has a support ring in the interior of the housing wherein the support ring is between the septum and the second end of the housing.

15 In an embodiment, a ring is attached to the cap wherein the ring forms an opening between the ring and the cap.

In an embodiment, the septum has a tapered exterior wall that is secured in the interior of the housing.

In an embodiment, the cap has a diameter smaller than a diameter of the septum.

20 In an embodiment, the support ring has a diameter greater than a diameter of the septum.

In another embodiment, a container is provided having peripheral walls defining an interior wherein the interior holds a solution. The container has a port having walls defined between a first end and a second end attached to the wall of the housing having an interior. A septum is provided in the interior of the port. Further, a support ring is provided in the interior of the port wherein the septum is between the support ring and the first end of the port and a cap enclosing the first end of the housing wherein the cap covers the septum.

25

In another embodiment, the container has a line of separation between the cap and the first end of the housing.

30

In another embodiment, the container has a target area in the septum defined by a recess formed in the septum.

In still a further embodiment, the container has a slit in the septum.

In an embodiment, the container has a port integrally formed with the cap.

In an embodiment, the container has a ring extending from the first end of the container wherein the ring defines an opening.

5 In another embodiment of the present invention, a method is provided for accessing a container. The method has the steps of: attaching a port having walls defined between a first end and a second end wherein the second end is attached to the wall of the container and further wherein the port has a cap at the first end of the port; securing a septum within the housing; securing a support ring within the housing
10 wherein the septum is between the support ring and the first end of the port; and removing the cap to expose only a portion of the septum.

In an embodiment, a needle is inserted through the septum.

In an embodiment, the cap is separated from the port at a line of separation.

In an embodiment, a ring is pulled having an opening attached to the cap to
15 remove the cap from the port.

In an embodiment, a recess area is formed in the septum wherein the septum has a slit.

In an embodiment, the walls of the port have a length between the first end and the second end greater than a combined width of the septum and the support ring.

20 It is, therefore, an advantage of the present invention to provide a port, a container and a method for accessing a container for the injection or withdrawal of a liquid from a container.

Another advantage of the present invention is to provide a port, a container and a method for accessing a port using a medication port having a target area located
25 under the cap.

Yet another advantage of the present invention is to provide a port, a container and a method for accessing a container which is compatible with a range of cannulas or needle gauges and lengths as well as with a range of insulin pens.

A still further advantage of the present invention is to provide a port, a
30 container and a method for accessing a container which allows for the port to be located away from an administration port providing simplified accessibility to both ports and/or without interference from the other port.

Moreover, an advantage of the present invention is to provide a port, a container and a method for accessing a container for using a medication port which decreases risk of contamination.

And, an advantage of the present invention is to provide a port, a container and
5 a method for accessing a container having a cap.

A still further advantage of the present invention is to provide a port, a container and a method for accessing a container having a rigid housing which reduces risk of cannula or needle sticking.

Additional features and advantages of the present invention are described in,
10 and will be apparent from, the detailed description of the presently preferred embodiments and from the drawings.

BRIEF DESCRIPTION OF THE FIGURES

Figure 1 illustrates a perspective view of a container with having a port in an embodiment of the present invention.

15 Figure 2 illustrates an exploded isometric view of a port in an embodiment of the present invention.

Figure 3 illustrates a sectional view of a cap on the port in an embodiment of the present invention.

20 Figure 4 illustrates a sectional view of a user removing a cap of the port in an embodiment of the present invention.

Figure 5 illustrates a sectional view of a needle inserted into the port in an embodiment of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

25 The present invention generally relates to a port, a container and a method for accessing a container for injecting or withdrawing a liquid from the container. Additionally, the present invention relates to a container having a port. More specifically, the present invention relates to a port, a container and a method for accessing a container to introduce a drug into the port.

30 Referring now to the drawings wherein like numerals refer to like parts, Figure 1 generally illustrates a perspective view of a container 1 having a first end 23 and a second end 24. The container 1 may be peripherally sealed and may have a liquid 5 or

other solution in an interior of the container 1. The container 1 may be constructed of a flexible material, such as a PVC or non-PVC material. Such containers are generally known and, as such, will not be described in further detail herein.

The container 1 may have a port 2 having a first end 18 and a second end 19.

5 The medication port 2 of the present invention may be an up-port or a side port. In the embodiment shown in Figure 1, the medication port 2 is a side-port. The container 1 is illustrated in a position as is common in actual use. More specifically, the container 1 may be positioned up-right and may have the medication port 2 elevated above an administration port 15 in actual use. Additionally, a strap 12 for, for example, a hook
10 may be provided to hang the container 1 in, for example, an elevated position at or near a patient. When the container 1 is positioned at or near the patient, gravity may force the liquid 5 inside the container 1 through the administration port 15 to the patient. Preferably, the administration port 15 may be located remotely from the medication port 2 as illustrated in the embodiment shown in Figure 1.

15 Referring now to Figure 2, the port 2 may have a housing 3 which may have a wall 25. Preferably, the port 2 is a medication port through which a medicament may be added or a solution may be removed from the container 1. The housing 3 and the wall 25 may be constructed from, for example, rubber, plastic or any other material generally known to those skilled in the art. Additionally, the housing 3 may be
20 constructed of rigid polypropylene which may reduce risk of a needle 7 puncturing the wall 25. Further, the housing 3 may be constructed using gamma-grade materials which are approved to withstand gamma irradiation prior to sterilization as a final stage of the manufacturing process. Gamma-grade materials allow for “pre-sterilization” and reduction in autoclaving exposure time.

25 As illustrated in Figure 2, the wall 25 may be circular. The wall 25 of the housing 3 may have a first end 26 and a second end 27. The second end 27 of the wall 25 may be integrally formed with the second end 19 of the medication port 2. Additionally, the first end 26 of the wall 25 may be integrally formed with a cap 9 wherein the cap 9 may be separated from the first end 26 which will be described in
30 further detail hereinafter.

The first end 26 of the wall 25 may also have a lip 39 which protrudes inward toward a center of the housing 3. The lip 39 may be in contact with a septum 4. The lip 39 may also secure the septum 4 within the housing 3 by friction, or, alternatively, the septum 4 may be sealed to the lip 39. The lip 39 of the wall 25 may have an inner
5 circumference 47 and an outer circumference 14 as shown in Figure 2.

The wall 25 may have a height 28 and may have a first circumference 30 at the first end 26 and a second circumference 32 at the second end 27. Additionally, the first circumference 30 at the first end 26 of the wall 25 may be smaller than the second circumference 32 at the second end 27 of the wall 25. The smaller circumference 30 at
10 the first end 26 of the wall 25 may result in the wall 25 being tapered. More specifically, a taper 31 may result in the wall 25 tilting inward toward the center of the housing 3. The septum 4 of the medication port 2 may be located within the wall 25 of the housing 3. Additionally, the septum 4 may be in contact with an inner wall 50 of the housing 3 as shown in Figure 3. The septum 4 may be constructed from, for
15 example, rubber, plastic or any other material generally known to those skilled in the art. Additionally, the septum 4 may be constructed of a polyisoprene material which may allow for the septum 4 to re-seal after puncturing the septum 4 by, for example, the needle 7.

As illustrated in Figure 2, the septum 4 may be circular. The septum 4 may
20 have a height 35 and may have a first circumference 36 and a second circumference 37. Additionally, the septum 4 may have a first end 33 and a second end 34. The first circumference 36 at the first end 33 of the septum 4 may be smaller than the second circumference 37 at the second end 34. The smaller circumference 36 at the first end 33 may result in the septum 4 being tapered. More specifically, a taper wall 38 may
25 result as shown in Figure 2 wherein an opening at a top side of the septum 4 is greater than at a center of the septum 4.

The first end 33 of the septum 4 may be in contact with the lip 39 of the wall 25. The lip 39 may secure the septum 4 in place within the housing 3 and may provide a liquid-tight fit between the septum 4 and the wall 25 of the housing 3.

30 The septum 4 may also have a target area 16 which may assist a health-care provider or other person with insertion of, for example, the needle 7 into the septum 4. Of course, a cannula or other object may be used to pierce the septum 4. The target

area 16 may also be colored, for example, red, to contrast with the color, for example, black, of the housing 3. Use of different colors may result in the target area 16 being more visible and/or distinguishable to the health-care provider or other person.

As further illustrated in Figure 2, a recess 21 may be located within the target area 16 of the first end 33 of the septum 4. The recess 21 may assist the health-care provider or other person by providing a reduced resistance location to insert the needle 7 through the septum 4. The target area 16 may also have a slit 54 instead of, or in addition to, the recess 21.

The recess 21 may be formed by an internal wall 8 in the target area 16 of the septum 4. More specifically, the wall 8 may have a first circumference 51 at the first end 33 of the septum and a second circumference 52 at a valley 53 within the septum 4. The first circumference 51 at the first end 33 of the septum 4 may be greater than the second circumference 52 at the valley 53 in the septum 4. The difference in the circumferences of the internal wall 8 may result in the internal wall 8 being tapered.

The health-care provider or other person may puncture the septum 4 to establish fluid communication with the liquid 5 in the container 1. A support ring 17 may support the septum 4 when an object, for example, the needle, is pressed down upon the septum 4. As illustrated in Figure 2, the support ring 17 may resemble, for example, a ring.

More specifically, when the health-care provider or other person inserts an object through the septum 4, pressure is created on the septum 4. The support ring 17 may allow pressure to be diverted from the outer periphery of the septum 4 onto the support ring 17. As a result, the septum 4 may be able to withstand a greater pressure with the support ring 17 than without the support ring 17. The support ring 17 may be constructed from, for example, rubber, plastic or any other material generally known to those skilled in the art.

The support ring 17 may be circular and may have a first outer circumference 44, a second outer circumference 49 and an inner circumference 45. Additionally, the support ring 17 may have a first end 40 and a second end 41. The first outer circumference 44 may be at the first end 40 and a second outer circumference 49 may be at the second end 41. The first outer circumference 44 may be greater than the second outer circumference 49. As a result, the support ring 17 may taper downward.

More specifically, the support ring 17 may have a taper 48. The first outer circumference 44 and the second outer circumference 49 of the support ring 17 may be in contact with the inner wall 50 of the housing 3 as shown in Figure 3.

The support ring 17 may also have a height 42 which may be smaller than the height 28 of the wall 25. The inner circumference 45 of the support ring 17 may form a hollow interior area 43 through which the needle 7 or other object may extend after piercing the septum 4.

The first end 40 of the support ring 17 may be in contact with the second end 34 of the septum 4. Additionally, the second end 41 of the support ring 17 may be in contact with a lip 13 on the container 1.

The housing 3 may also have a cap 9 that may be constructed from, for example, rubber, plastic or any other material generally known to those skilled in the art. The cap 9 of the housing 3 may have a cover 11 having a circumference 46. The cap 9 may also have a ring handle 10. As illustrated in Figure 2, the cover 11 and the ring handle 10 may be circular. The ring handle 10 of the cap 9 may have a hollow opening 6 through which a user may insert, for example, a finger or hook.

The cover 11 of the cap 9 may also have a line of separation 20. The line of separation 20 may be a perforation, a score line or other line of weakness formed between the cover 11 and the lip 39 of the wall 25. The line of separation 20 may be formed at the circumference 46 of the cover 11. More specifically, the line of separation 20 may provide a circumferential point at which the cover 11 may be removed from a remainder of the housing 3.

The cover 11 may be integrally formed with the ring handle 10 by a connector 22 as generally shown in Figure 2. The connector 22 may be secured to the cover 11 and the ring handle 10 so that a pulling force may break the line of separation 20.

Figure 3 illustrates an embodiment of the medication port 2 of the present invention with the cap 9 secured to the wall 25 of the housing 3. More specifically, Figure 3 illustrates the medication port 2 prior to removal of the cap 9.

When the cap 9 is on the housing 3, the cap 9 may protect the septum 4 and may create a sterile environment for the septum 4 by sealing the septum 4 from the surrounding environment. More specifically, when the cap 9 is secured to the wall 25

of the housing 3, dust, pathogens and other harmful substances may not access the septum 4 located within the housing 3.

Additionally, when the cap 9 is in the sealed position, the septum 4 may be protected from physical damage. The cap 9 may prevent accidental damage that may otherwise occur to the septum 4 if the septum 4 was unprotected.

Figure 4 illustrates an embodiment of the present invention with the cap 9 of the medication port partially removed. The ring handle 10 of the cap 9 may be lifted by, for example, a finger of a user or a hook. When the user pulls on the ring handle 10, the line of separation 20 may break and may allow the user to remove the cap 9. When the cap 9 is removed, the septum 4 may be exposed. Upon removal of the cap 9, the septum 4 may be ready for use through penetration of the septum 4 by, for example, the needle 7.

Figure 5 illustrates an embodiment of the medication port 2 of the present invention with the cap 9 removed from the wall 25 of the housing 3. Figure 5 also illustrates the needle 7 inserted through the septum 4 to provide fluid communication with the liquid 5 inside the interior of the container 1.

The septum 4 may be punctured by the needle 7 or cannula (not shown). The needle 7 or other object may pierce the septum 4 through the target area 16 on the septum 4. The needle 7 or other object may then pass through the hollow interior 43 of the support ring 17. After the needle or other object is inserted into the container 1, liquid may be added or withdrawn to from the container 1 as may be required.

It should be understood that various changes and modifications to the presently preferred embodiments described herein will be apparent to those skilled in the art. Such changes and modifications may be made without departing from the spirit and scope of the present invention and without diminishing its attendant advantages. It is, therefore, intended that such changes and modifications be covered by the appended claims.

CLAIMS

The invention is claimed as follows:

1. A port comprising:
a housing having an interior defined by peripheral walls extending between a
5 first end and a second end;
a septum within the interior at the first end of the housing;
a cap on the first end of the peripheral walls of the housing wherein the cap
encloses the first end of the housing and covers the septum; and
a line of separation between the cap and the peripheral walls of the housing.
10
2. The medication port of Claim 1 further comprising:
a lip extending between the peripheral walls and the cap at the first end of the
housing.
- 15 3. The medication port of Claim 1 further comprising:
a recess formed in the septum wherein the recess includes a slit.
4. The medication port of Claim 1 further comprising:
a support ring in the interior of the housing wherein the support ring is
20 between the septum and the second end of the housing.
5. The medication port of Claim 1 further comprising:
a ring attached to the cap wherein the ring forms an opening between the
ring and the cap.
25
6. The medication port of Claim 1 wherein the septum has a tapered exterior
wall that is secured in the interior of the housing.
7. The medication port of Claim 1 wherein the cap has a diameter smaller than
30 a diameter of the septum.

8. The medication port of Claim 4 wherein the support ring has a diameter greater than a diameter of the septum.

9. A container comprising:
5 peripheral walls defining an interior wherein the interior holds a solution;
a port having walls defining an interior between a first end and a second end wherein the port is attached to the wall of the housing;
a septum in the interior of the port;
a support ring in the interior of the port wherein the septum is between the
10 support ring and the first end of the port; and
a cap enclosing the first end of the housing wherein the cap covers the septum.

10. The container of Claim 9 further comprising:
a line of separation between the cap and the first end of the housing.

15

11. The container of Claim 9 further comprising:
a target area in the septum defined by a recess formed in the septum.

12. The container of Claim 9 further comprising:
20 a slit in the septum.

13. The container of Claim 9 wherein the port is integrally formed with the cap.

25 14. The container of Claim 9 further comprising:
a ring extending from the first end of the container wherein the ring defines an opening.

15. A method for accessing a container wherein the container has walls
30 defining an interior, the method comprising the steps of:

attaching a port having walls defined between a first end and a second end wherein the second end is attached to the wall of the container and further wherein the port has a cap at the first end of the port;

securing a septum within the housing;

5 securing a support ring within the housing wherein the septum is between the support ring and the first end of the port;

removing the cap to expose only a portion of the septum.

16. The method of Claim 15 further comprising the step of:
10 inserting a needle through the septum.

17. The method of Claim 15 further comprising the step of:
separating the cap from the port at a line of separation.

15 18. The method of Claim 15 further comprising the step of:
pulling a ring having an opening attached to the cap to remove the cap from the
port.

19. The method of Claim 15 further comprising the step of:
20 forming a recessed area in the septum wherein the septum has a slit.

20. The method of Claim 15 wherein the walls of the port have a length between the first end and the second end greater than a combined width of the septum and the support ring.

25

FIG.1

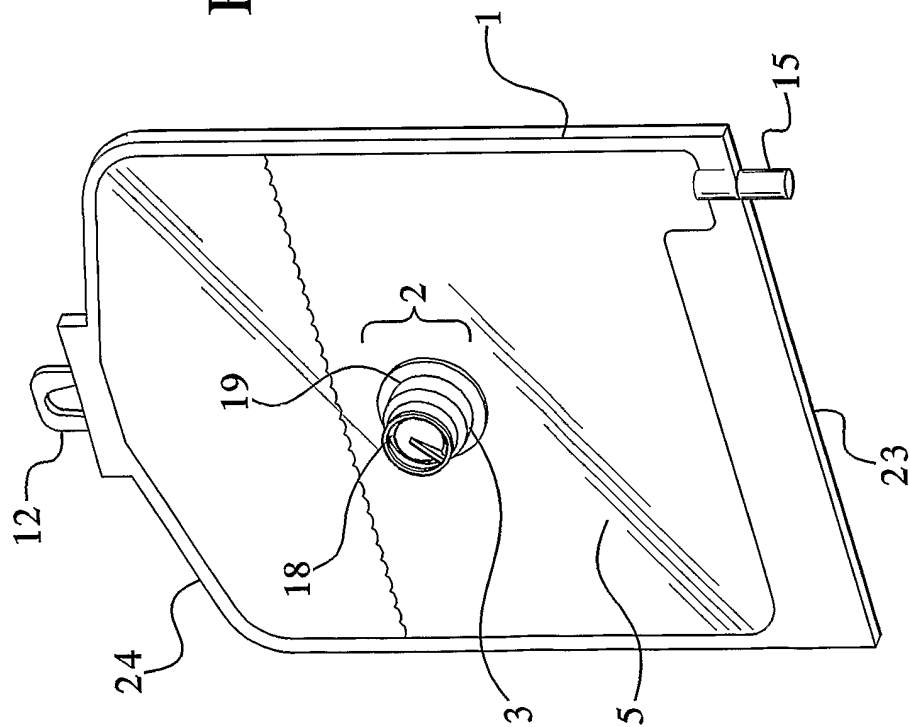
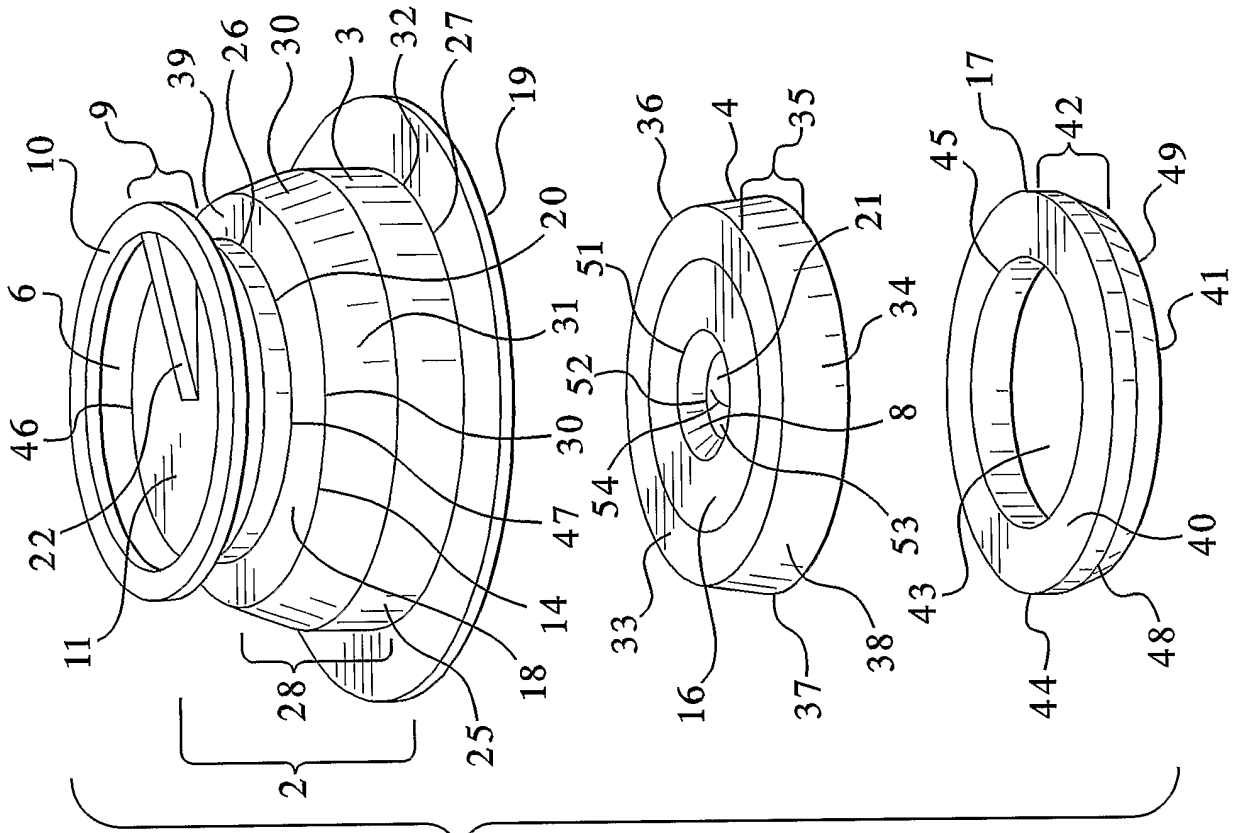
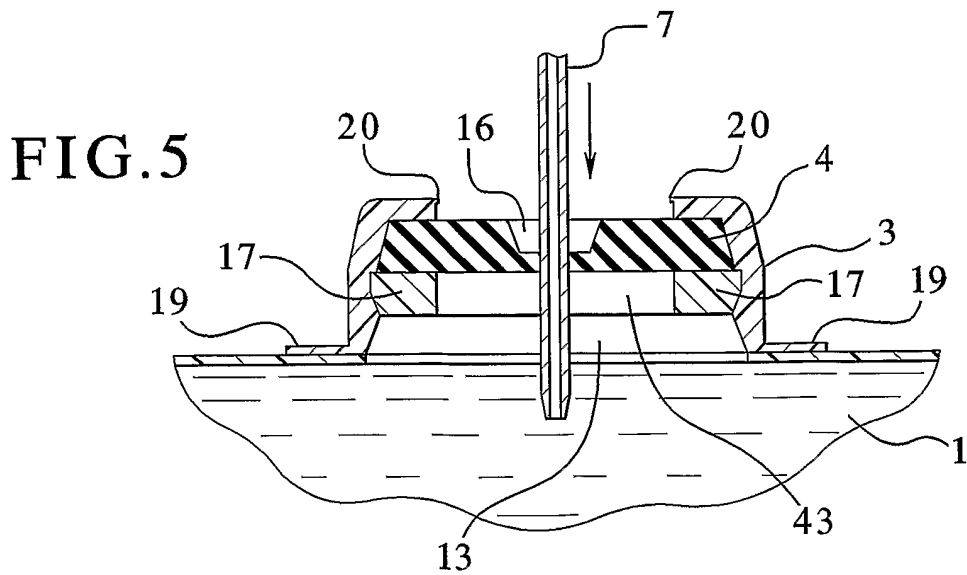
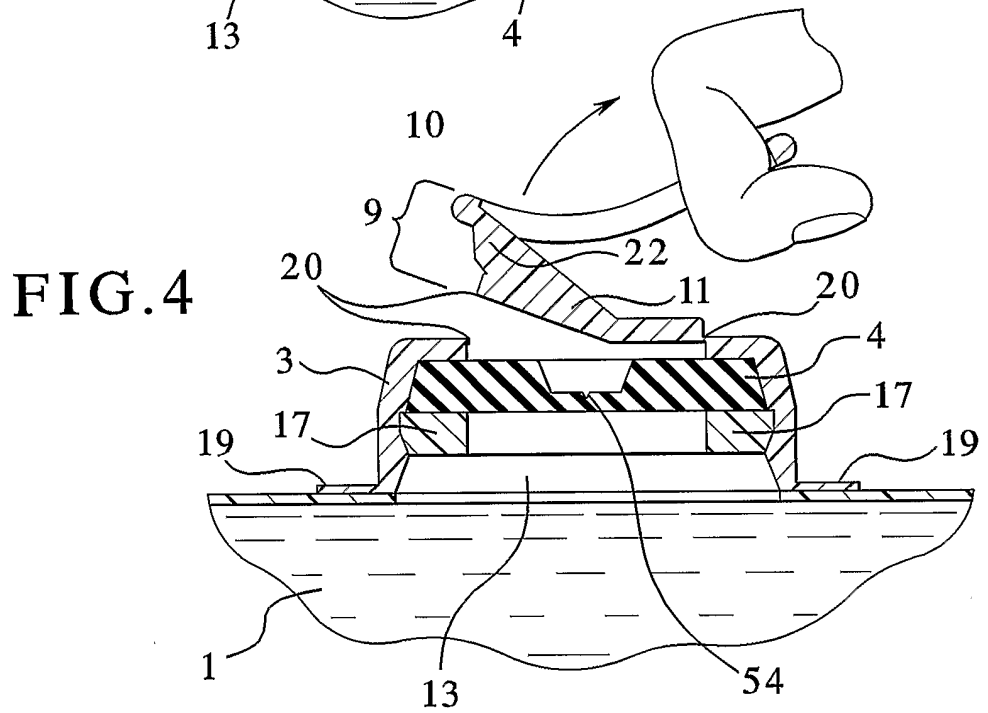
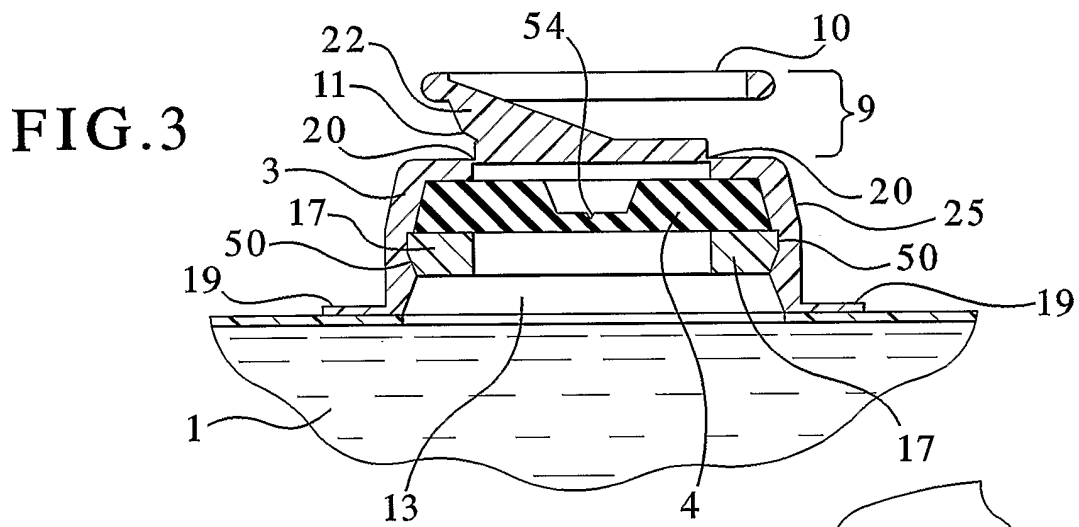


FIG.2





INTERNATIONAL SEARCH REPORT

PCT/US 03/16835

A. CLASSIFICATION OF SUBJECT MATTER IPC 7 A61J1/05		
According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED		
Minimum documentation searched (classification system followed by classification symbols) IPC 7 A61J B65D		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practical, search terms used) EPO-Internal, WPI Data, PAJ		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DE 43 27 845 A (MATTHIAS FAENSEN GMBH & CO KG) 2 March 1995 (1995-03-02) column 2, line 8 -column 3, line 14; figure	1-20
X	EP 0 011 144 A (BIOTEST SERUM INSTITUT GMBH) 28 May 1980 (1980-05-28) page 3, line 25 -page 6, line 21 page 7, line 19 - line 29; figure 2	1-12, 14-20
X	DE 100 30 474 C (FRESENIUS KABI DE GMBH) 21 February 2002 (2002-02-21) paragraphs '0021!', '0022!', '0028!; figures 1,3	1-3,6,7
A	---	4,5,8-20
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<input checked="" type="checkbox"/> Further documents are listed in the continuation of box C. <input checked="" type="checkbox"/> Patent family members are listed in annex.		
° Special categories of cited documents :		
A document defining the general state of the art which is not considered to be of particular relevance *E* earlier document but published on or after the international filing date *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) *O* document referring to an oral disclosure, use, exhibition or other means *P* document published prior to the international filing date but later than the priority date claimed		*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art. *&* document member of the same patent family
Date of the actual completion of the international search 25 August 2003		Date of mailing of the international search report 09/09/2003
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016		Authorized officer Fischer, E

INTERNATIONAL SEARCH REPORT

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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