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(54) Title: SNAP-OVER PORT CAP

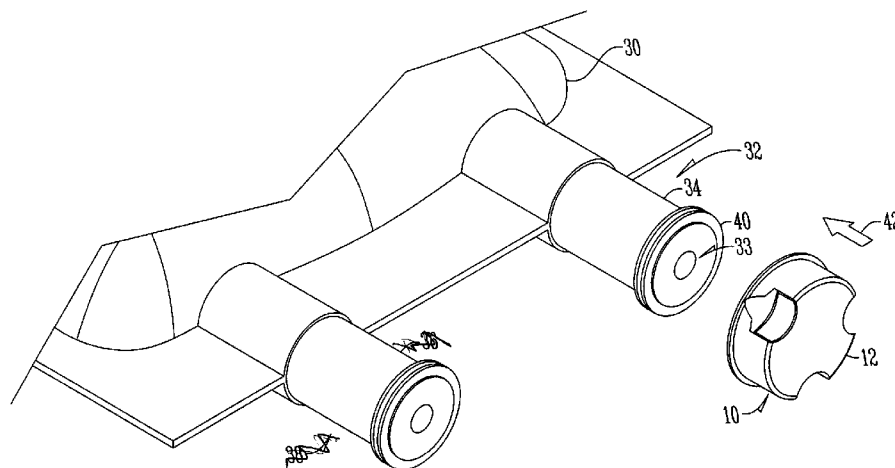


Fig. 4

(57) Abstract: A single-use, snap-over cap for use primarily in healthcare settings in order to maintain the integrity of a medication solution. The cap has a tapered cylindrical skirt, a puncture resistant lid portion, and one or more latch tabs. When placed onto a flanged injection port such as is found on a conventional fluid container, the latch tabs engage and flex about the port flange. After the cap is placed, the latch tabs engage the port flange to prevent upward axial movement relative to the port, thereby preventing removal of the cap and thus deterring unwanted or erroneous drug administrations or withdrawals.

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TITLE: SNAP-OVER PORT CAP

BACKGROUND OF THE INVENTION

[0001] The present invention relates to the field of containers for administering medical fluids to patients. More particularly, the present invention relates to a snap-over port cap for intravenous (IV) fluid containers.

[0002] Access ports are commonly used in infusion solution containers to administer solutions to a patient, or to add medicaments or other solutions to the container prior to administration. Current solution containers typically may include a dedicated outlet port for solution administration to a patient and a dedicated inlet port for the addition of diluent or other ingredients to the container. These ports are conventional in the art and may be of different types of construction but typically have an annular flange. The ports are in fluid communication with the container, usually via an attached tube having a diameter smaller than the port flange.

[0003] The outlet port is intended to be coupled to an administrative set and is therefore commonly referred to as the administrative port, whereas the inlet port is designed to permit the injection of therapeutic agents and nutrients into the partially filled container and is sometimes identified as the additive or injection port. Such a container may contain a partial filling of a sterile solution such as saline or dextrose to function as a diluent for the injected additive. The diluted drug or nutrient is then administered to a patient by means of the administrative set that may be either directly or indirectly (i.e., through another solution set) coupled to the patient.

[0004] Maintaining the integrity of medication solutions to be

administered to a patient is of major importance. It has been found, however, that careless or inattentive handling of a solution container may create significant risks of drug administration errors. Such errors include duplicate administrations of the same substance (overdosing) as well as mis-administration of the wrong substance. These risks may be increased where emergency situations are presented that require quick manipulation of the various components and quick addition of one or more substances to a container via the additive port. In extreme circumstances, a person may intentionally seek to harm a patient by adding one or more agents. Likewise, one could deliberately remove properly mixed solutions via the additive port for illicit purposes. It is imperative that evidence of such tampering be readily apparent to caregivers or their supervisors.

[0005] Current methods of making notification of a previous drug administration include placing an adhesive label over the face of the port or onto the container itself. Adhesive labels are not mechanically attached to the port or the container, may be removed, and do not offer any resistance to subsequent needle penetration.

[0006] Therefore, an object of this invention is to provide an additive port cap closure that is readily available and easy to place on a port, fully covering the same, upon the completion of prescribed drug admixtures.

[0007] A further object of the invention is to provide an additive port cap that cannot be removed without damaging the cap and/or the underlying port, and/or leaving visible evidence of tampering.

[0008] Another object of the invention is to provide an additive port cap that is puncture resistant so as to deter the administration or removal of one or more substances via

syringe after the cap is in place.

[0009] Yet another object of the invention is to provide an additive port cap that is easy and inexpensive to manufacture.

[0010] These and other objects will be apparent to those skilled in the art.

SUMMARY OF THE INVENTION

[0011] A snap-over port cap is provided for use primarily in clinical healthcare settings, such as hospital pharmacies. Specifically, the cap is designed to be placed over an injection or additive port on a conventional IV fluid container or the like.

[0012] In a typical scenario, one or more substances are added to the container through the injection port using a conventional syringe. In order to deter unwanted or erroneous drug administrations or withdrawals, the snap-over port cap is immediately placed over the injection or additive port. The cap is intended for a single use, is disposable and cannot be removed, tampered with or compromised without damaging the cap or at the very least conspicuously stressing or deforming the cap material to give a visible indicator of the disrupting activity.

[0013] The cap comprises a puncture resistant lid portion, a tapered cylindrical skirt, and one or more latch tabs provided about the cylindrical skirt. The latch tabs flex under moderate pressure, typically as the cap is manually placed downward over an annular flange situated about the port. The diameter of the lid portion is larger than the diameter of the access site about the port, covering that portion of the port utilized for administrations. The base of the tapered skirt is of slightly larger diameter than the flange. As the latch tabs flex, one or more projections engage the annular flange.

As the cap is further depressed, the projections clear the flange and return to a non-flexed or relaxed position. Upward axial movement relative to the port is deterred by the engagement between the projections and the flange, and the cap is maintained in place.

[0014] Attempts to forcibly remove the cap from the port will cause visible deformation or destructive change to the cap, particularly to the latch tabs, and possibly to the port and/or the container.

BRIEF DESCRIPTION OF THE DRAWINGS

[0015] Fig. 1 is a front view of a port cap;

[0016] Fig. 2A is top-plan view of a port cap;

[0017] Fig. 2B is a partial cross-section of a port cap taken along line A-A of Figure 2A;

[0018] Fig. 3A is a top-plan view of an alternative embodiment of a port cap;

[0019] Fig. 3B is a partial cross-section of a port cap taken along line B-B of Figure 3A;

[0020] Fig. 4 is a perspective view illustrating a port cap being positioned about a conventional port;

[0021] Fig. 5 is a cross-section of a port cap in an intermediate position while being placed about a conventional port; and

[0022] Fig. 6 is a cross-section of a port cap in place about a conventional port.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

[0023] The embodiments discussed herein are merely illustrative of specific manners in which to make and use the invention and are not to be interpreted as limiting the scope of the instant invention.

[0024] While the invention has been described with a certain degree of particularity, it is to be noted that many modifications may be made in the details of the invention's construction and the arrangement of its components without departing from the scope of this disclosure. It is understood that the invention is not limited to the embodiments set forth herein for purposes of exemplification.

[0025] Referring to Fig. 1, cap 10 comprises a closed end or lid portion 12 and a tapered cylindrical skirt 14. Skirt 14 has a base 16 opposite said lid portion 12. One or more latch tabs 18 are situated about base 16 of skirt 14. In a preferred embodiment, three axisymmetric latch tabs 18 are provided, spaced evenly about the circumference of base 16. It should be appreciated, however, that virtually any number of latch tabs may be provided in any number of orientations. Separating each latch tab 18 from lid portion 12 is an aperture 20. It will be appreciated that the presence of one or more apertures 20 facilitates molding. An optional outwardly protruding rim 21 can be provided on the base 16 for strength and stress control.

[0026] Skirt 14 is tapered such that the diameter of lid portion 12 is less than the diameter of base 16. Skirt 14 is constructed of a substantially rigid material, such as polypropylene or suitable plastic. Lid portion 12 is also constructed of a rigid material, such as polypropylene or suitable plastic, and is preferably of sufficient thickness to provide puncture resistance to conventional hypodermic needles. Lid portion 12 and skirt 14 may be molded as a unitary cap 10 using conventional techniques.

[0027] Turning to Figs. 2A and 2B, each latch tab 18 comprises a first projection 22. Projection 22 extends and is angled upwardly and inwardly from base 16 toward lid portion 12.

Projection 22 is preferably conical, frusto-conical or in the shape of a smooth partial cone. First projection 22 has a terminal end 24 that is situated wholly within the diameter of tapered skirt 14, forming a ledge at the bottom of aperture 20.

[0028] An alternative embodiment of cap 10 is illustrated in Figs. 3A and 3B, wherein a second projection 26 is provided. Second projection 26 extends upward from base 16 toward lid portion 12. Second projection 26 is essentially vertical, forming a plane that is roughly perpendicular to the plane defined by lid portion 12. Second projection 26 has a terminal end 28 that defines a bottom edge of aperture 20. The ledge formed by terminal end 24 of first projection 22 sits beneath terminal end 28 of second projection 26.

[0029] Now referring to Fig. 4, conventional solution container 30 has an additive or inlet port 32, an access site 33 about inlet port 32, an inlet tube 34. Situated about inlet port 32 is annular flange 40. Access site 33 is typically centrally located about inlet port 32 and commonly includes a reseal element or reseal member that is elastomeric and self-resealing; 'access site' is used herein to denote that portion of the port through which substances are added or withdrawn, without limitation.

[0030] The diameter of lid portion 12 is larger than the diameter of access site 33. Accounting for apertures 20, the surface area of lid portion 12 is still greater than the surface area of access site 33 such that when cap 10 is in place, lid portion 12 (or at least a diameter thereof by the aperture 20) fully covers access site 33. The diameter of base 16 is slightly larger than the diameter of flange 40. Terminal ends 24 of first projections 22 define an internal diameter within cap 10 that is smaller than the diameter of

flange 40.

[0031] Once all desired medications, drugs and other substances have been added to container 30 in any conventional manner, cap 10 is placed over the additive or inlet port 32 with lid portion 12 facing outward and with the interior of cap 10 facing inlet port 32. First projections 22 are in a non-flexed or relaxed position, as best shown in Figs. 2B and 3B. Referring again to Fig., pressure is applied to cap 10 in the direction of arrow 42, causing latch tabs 18 to flex outwardly to allow flange 40 to pass through. Thereafter, first projections 22 deter removal of cap 10 due to interference between flange 40 and first projections 22. Minimum pressure to cause flexion of first projections 22 as described herein is preferably between 10-14 pounds per square inch.

[0032] As latch tabs 18 engage flange 40, first projections 22 flex or bend upwardly and outwardly, as best shown in Fig. 5. First projections 22 bend within range of flex travel 44. As cap 10 continues downward in direction 42, flange 40 clears terminal end 24 of first projection 22, and first projection 22 returns to its non-flexed or relaxed position, angled inwardly and upwardly toward lid portion 12. See Fig. 6. A segment of flange 40 is received within aperture 20. Access site 33 of inlet port 32 is fully covered by lid portion 12.

[0033] Still referring to Fig. 6, it should be appreciated that if one attempts to remove cap 10 by applying axial pulling force in the direction of arrow 46, terminal end 24 of first projection 22 will engage flange 40 and deter further axial movement. Rotational movement of cap 10 about inlet port 32 is possible, but this is not a limitation. Depending upon the structure of inlet port 32 and/or the thickness of flange 40, cap 10 may or may not freely rotate.

[0034] Latch tabs 18 serve as tensile stress concentrators.

Attempts to force cap 10 in direction 46, as well as attempts to force first projections 22 open, will result in the fracture of first projections 22 or at the very least cause a visible deformation of one or more portions of latch tab 18, including second projections 24, as well as surrounding skirt 14 and base 16. Deformations could include, but are not limited to, discoloration, stressing, and creasing. Likewise, persons skilled in the art will appreciate that attempts to pry cap 10 away from inlet port 32 will result in deformations to cap 10, and could additionally result in deformations and/or destructive changes to inlet port 32, inlet tube 34 or even container 30.

[0035] Caps 10 may be color coded to facilitate identification of certain types of medical solutions. For example, red caps may be provided for hazardous agents such as oncolytics, while purple caps may be provided for general drug administrations. Persons skilled in the art will appreciate that there are a number of color-coding conventions in the clinical setting, and that there are potentially limitless color combinations.

[0036] Whereas, the present invention has been described in relation to the drawings attached hereto, it should be understood that other and further modifications, apart from those shown or suggested herein, may be made within the scope of this invention.

What is claimed is:

1. A snap-over cap for a port having a flange, comprising:
a tapered cylindrical skirt having a base; and
a lid portion at the end of said skirt opposite said base;
wherein said skirt has a latch tab situated about said base,
said latch tab being adapted to engage an annular flange about
a port, and wherein said latch tab further comprises a first
projection extending upward and inward from said base toward
said lid portion, said first projection being substantially
conical in shape.
2. The cap of claim 1 wherein an aperture is provided
between said latch tab and said lid portion, said aperture
being adapted to receive a segment of said annular flange.
3. The cap of claim 1 wherein said latch tab engages said
flange so as to prevent axial movement of said cap in a
direction away from said port.
4. The cap of claim 1 wherein said skirt and said latch tab
are substantially rigid.
5. The cap of claim 4 wherein said first projection flexes
outward when engaged by said flange under pressure greater
than ten pounds per square inch.
6. The cap of claim 1 wherein the lid portion is puncture
resistant.
7. The cap of claim 1 wherein the diameter of said lid
portion is greater than the diameter of an access site on said

port.

8. The cap of claim 1 wherein the surface area of said lid portion is greater than the surface area of an access site on said port.

9. The cap of claim 1 wherein the cap is color coded to denote a specific class of substances.

10. The cap of claim 1 comprising a plurality of latch tabs that are axisymmetric about said cap.

11. The cap of claim 1 wherein said latch tab further comprises a second projection extending upward toward said lid portion.

12. The cap of claim 11 wherein said second projection defines a plane perpendicular to said lid portion.

13. A snap-over cap for a port having a flange, comprising:
a tapered cylindrical skirt having a base;
a puncture resistant lid portion at an end of said skirt
 opposite said base, said lid portion fully having a
 diameter covering an access site on a port;
a plurality of axisymmetric latch tabs situated about said
 base, said latch tabs being adapted to engage an annular
 flange about said port, and wherein said latch tabs
 further comprise a first projection extending angularly
 upward and inward toward said lid portion, said first
 projection being substantially conical in shape; and
an aperture provided between each of said latch tabs and said
 lid portion, each aperture being adapted to receive a

segment of said annular flange; and defining a portion of said diameter fully covering said access site.

14. The cap of claim 13 wherein said latch tabs further comprise a second projection extending upward toward and roughly perpendicular to said lid portion.

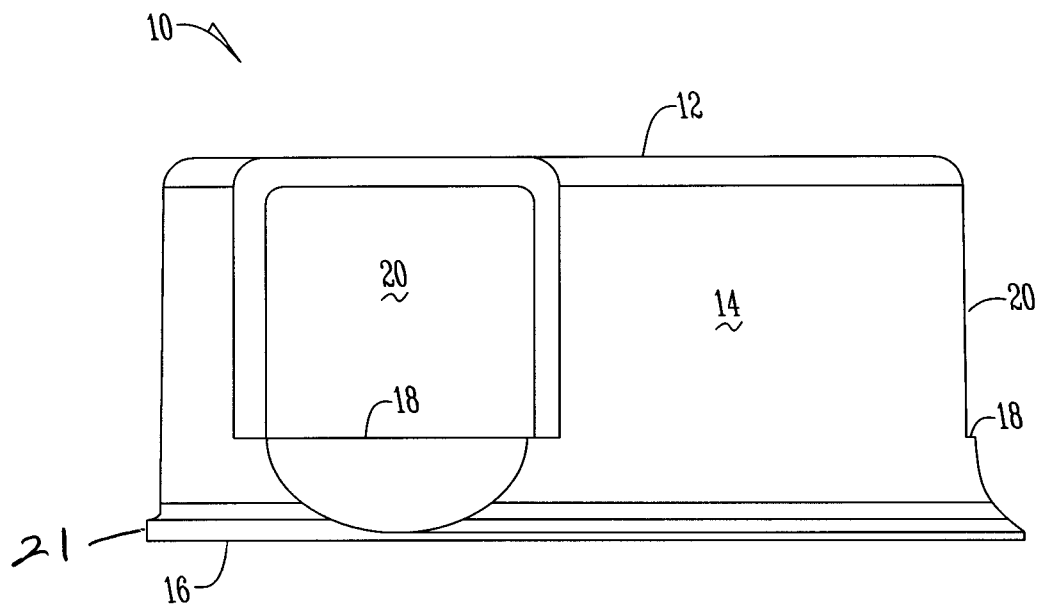


Fig. 1

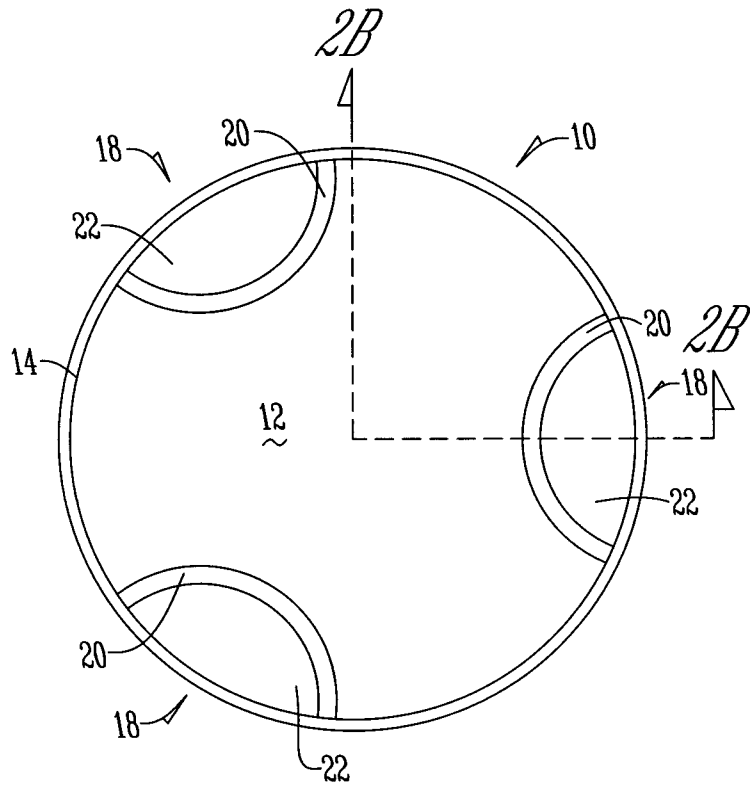


Fig. 2A

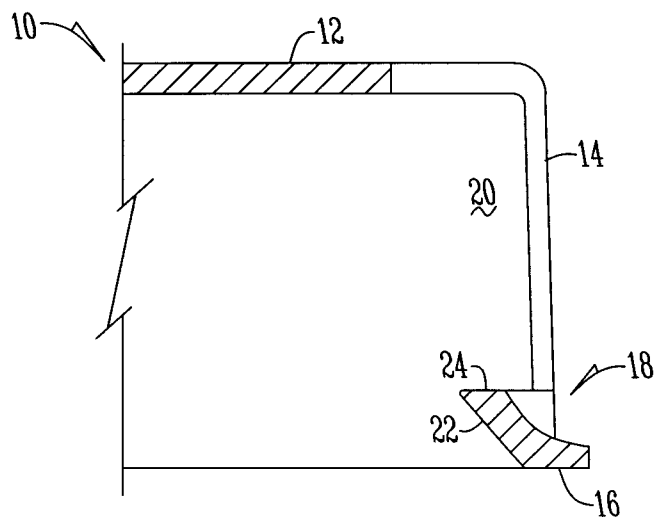


Fig. 2B

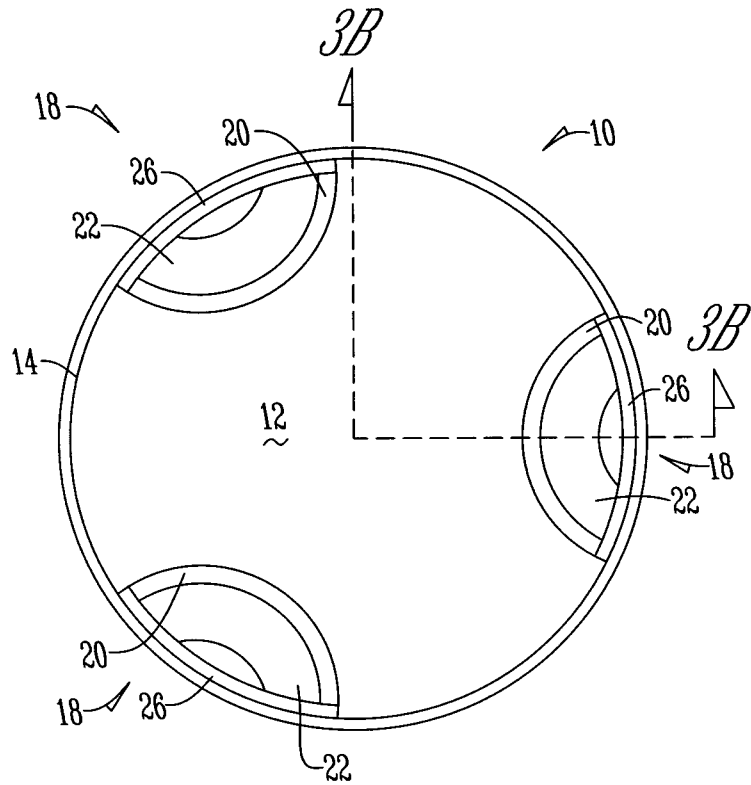


Fig. 3A

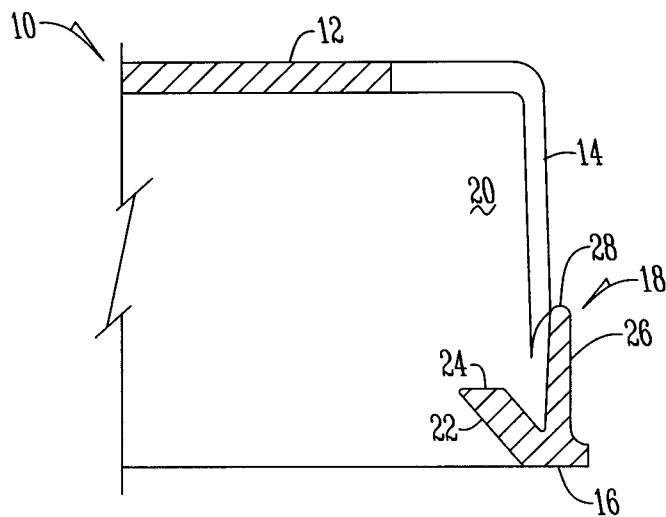


Fig. 3B

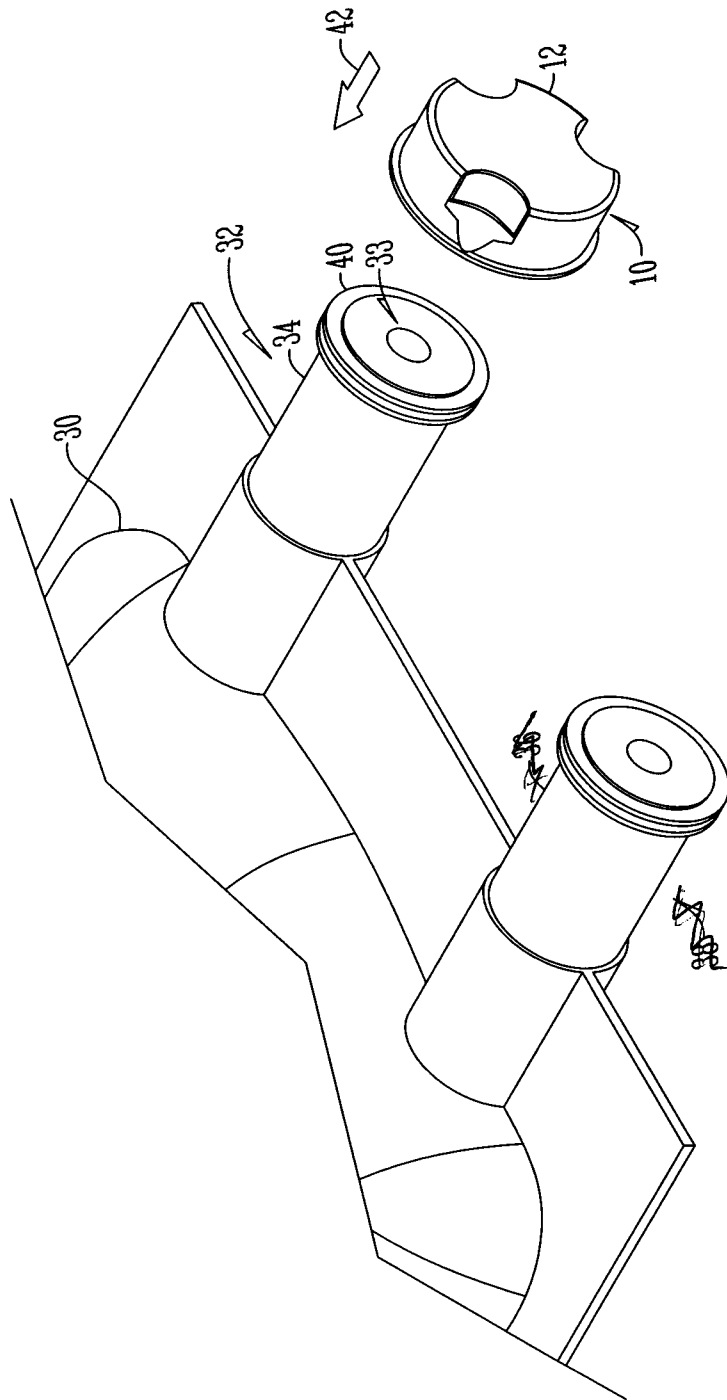


Fig. 4

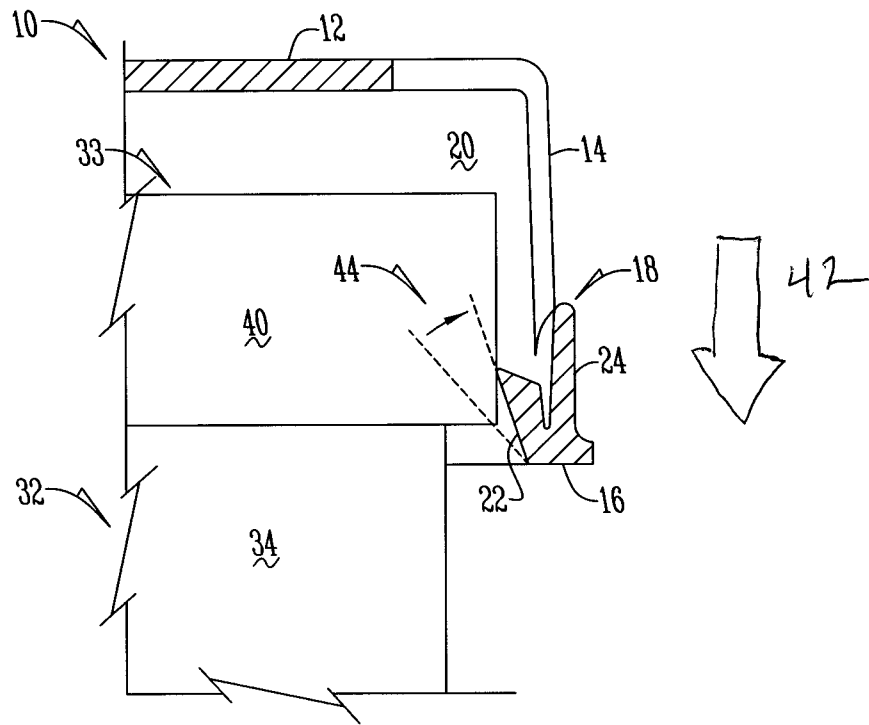


Fig. 5

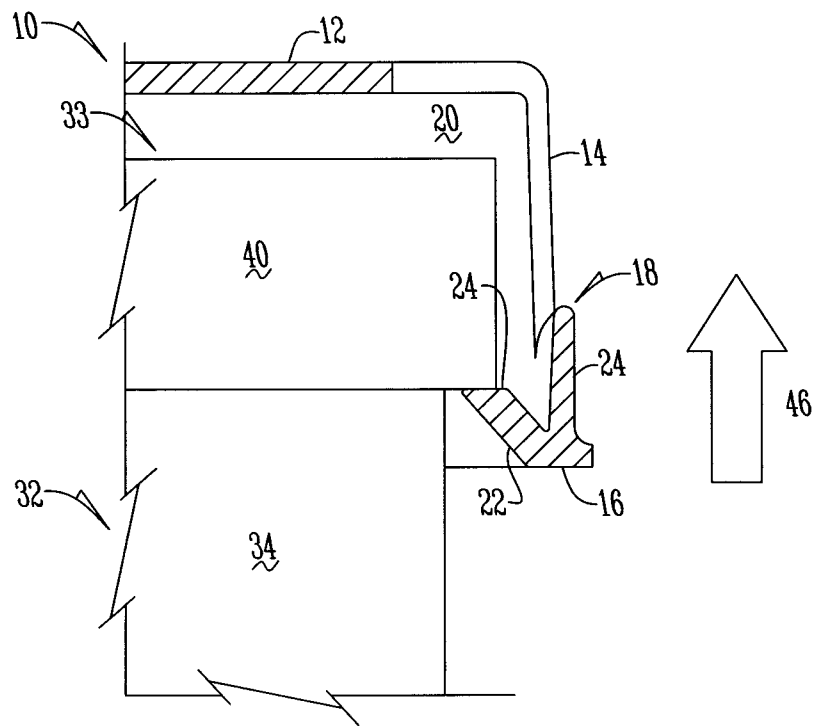


Fig. 6

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2008/078411

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - B65D 41/16 (2008.04)
USPC - 220/780
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(8) - B65D 41/16, 41/46 (2008.04)
USPC - 215/202, 216, 225, 317, 353; 220/780, 784; 383/67, 80

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 practicable, search terms used)
USPTO EAST System (US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT), PatBase

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 1,191,567 A (CLAY) 18 July 1916 (18.07.1916) entire document	1-10
Y	US 2006/0163265 A1 (DE CANDIDO) 27 July 2006 (27.07.2006) entire document	11, 12
Y	US 5,538,154 A (VON HOLDT) 23 July 1996 (23.07.1996) entire document	11, 12
A	US 1,027,330 A (HAMMER) 21 May 1912 (21.05.1912) entire document	1-14
A	US 2007/0062949 A1 (BORDNER) 22 March 2007 (22.03.2007) entire document	1-14
A	US 4,260,067 A (ANDRUCHIW) 07 April 1981 (07.04.1981) entire document	1-14
A	US 6,165,161 A (YORK et al) 26 December 2000 (26.12.2000) entire document	1-14

Further documents are listed in the continuation of Box C.

* Special categories of cited documents:	"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
"A" document defining the general state of the art which is not considered to be of particular relevance	"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
"E" earlier application or patent but published on or after the international filing date	"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
"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)	"&" document member of the same patent family
"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	

Date of the actual completion of the international search 21 November 2008	Date of mailing of the international search report 01 DEC 2008
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