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[Continued on next page]

(54) Title: NEEDLELESS CONNECTOR WITH FOLDING VALVE

(57) **Abstract:** A needleless connector has a body having an internal cavity with a sealing ridge, a port, an output flow channel, and a fluid flow path between the port and output flow channel. The connector also has a collapsible valve disposed within the cavity. The valve includes a cylindrical wall having a center axis and a shoulder and defining an internal air space, wherein the shoulder is configured to sealingly contact the ridge of the body so as to block the fluid flow path, and a head fixedly attached to the wall, the head having first and second smiley cuts disposed on opposite sides of the head.

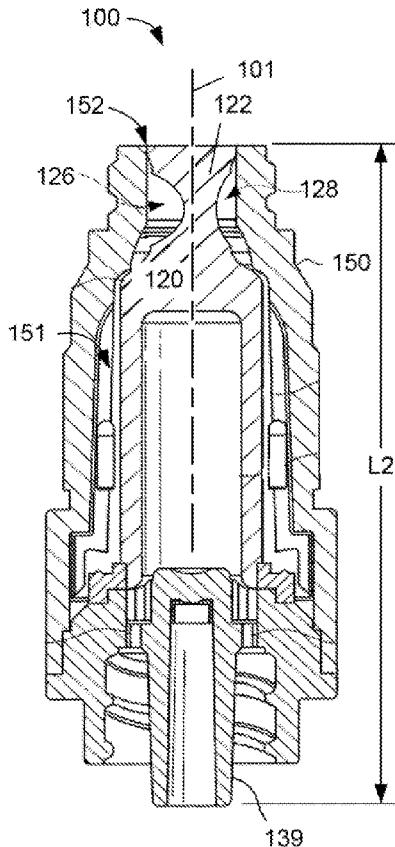


FIG. 2A



DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

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## NEEDLELESS CONNECTOR WITH FOLDING VALVE

Cross-references to related applications

[0001] Not applicable.

### BACKGROUND

Field

[0002] The present disclosure generally relates to needleless connectors, and, in particular, to connectors with an internal collapsible valve.

Description of the Related Art

[0003] Medical treatments often include the infusion of a medical fluid, for example a saline solution or a liquid medication, to patients using an intravenous (IV) catheter that is connected through an arrangement of flexible tubing and fittings, commonly referred to as an “IV set,” to a source of fluid, for example an IV bag. The fittings commonly include interconnectable male and female needleless connectors having a “Luer taper” conforming to an International Standards Organization (ISO) standard. Certain connectors have a self-sealing feature to prevent leakage of fluid from the attached tubing when the connector is decoupled from a mating connector.

[0004] One conventional needleless valve, shown in FIGS. 1A-1B, has a collapsible internal valve made of a flexible material. When a force is applied to the top of the valve by the tip of a male Luer connector, the valve folds at a “smiley cut” located in the upper portion, referred to as the “head” of the valve, thereby opening a flow path through the connector. As the size of this type of connector is reduced, however, the behavior of the flexible valve may not scale and the valve having a single smiley cut may not fold at the desired amount of force.

[0005] Most needleless connectors trap some amount of fluid when the connector is disconnected from a previously mated connector. As some medical fluids degrade with time, this trapped fluid may present a hazard to a patient.

## SUMMARY

[0006] The self-sealing needleless female Luer connector disclosed herein is reduced in size compared to conventional connectors of the same type and, therefore, may trap a reduced amount of fluid within the connector upon disconnection. The disclosed connector also accepts a standard male Luer fitting and provides a self-sealing port with a continuous external surface at the port when the connector is not activated such that the port may be disinfected prior to use.

[0007] In certain embodiments, a needleless connector is disclosed that includes a body having an internal cavity with a sealing ridge, a port, an output flow channel, and a fluid flow path between the port and output flow channel. The connector also includes a collapsible valve disposed within the cavity. The valve has a cylindrical wall having a center axis and a shoulder and defining an internal air space, wherein the shoulder is configured to sealingly contact the ridge of the body so as to block the fluid flow path, and a head fixedly attached to the wall. The head has first and second smiley cuts disposed on opposite sides of the head.

[0008] In certain embodiments, a collapsible valve is disclosed that includes a cylindrical wall having a center axis and defining an internal air space and a head fixedly attached to the wall. The head has first and second smiley cuts disposed on opposite sides of the head.

## BRIEF DESCRIPTION OF THE DRAWINGS

[0009] The accompanying drawings, which are included to provide further understanding and are incorporated in and constitute a part of this specification, illustrate disclosed embodiments and together with the description serve to explain the principles of the disclosed embodiments. In the drawings:

[0010] FIGS. 1A-1B are cross-sections of a conventional needleless connector.

[0011] FIGS. 2A-2B are cross-sections of an exemplary needleless connector according to certain aspects of the present disclosure.

[0012] FIGS. 3-5 are side views of various example embodiments of the head of a valve according to certain aspects of the present disclosure.

## DETAILED DESCRIPTION

[0013] It is advantageous to provide a self-sealing, needleless connector that accepts male Luer fittings that meet the ISO standard while the size of the connector, and therefore the volume of fluid within the connector, is reduced compared to conventional connectors.

[0014] In the following detailed description, numerous specific details are set forth to provide a full understanding of the present disclosure. It will be apparent, however, to one ordinarily skilled in the art that embodiments of the present disclosure may be practiced without some of the specific details. In other instances, well-known structures and techniques have not been shown in detail so as not to obscure the disclosure. In the referenced drawings, like numbered elements are the same or essentially similar. Reference numbers may have letter suffixes appended to indicate separate instances of a common element while being referred to generically by the same number without a suffix letter.

[0015] FIGS. 1A-1B are cross-sections of a conventional needleless connector 10. With reference to FIG. 1A, the connector 10 includes a collapsible valve 20 disposed within a cavity 51 of body 50. The valve 20 has a shoulder 30 that continuously contacts a ridge 54 within the cavity 51 when the connector 10 is de-activated, *i.e.* not connected to a mating connector, to form a primary seal that blocks the fluid flow path through the connector 10. The valve 20 has an internal air space 32 that is separated from the cavity 51 by a cylindrical wall 28. The air space 32 is vented to the ambient environment through air passages 56 and the external cavity 58 within the threaded connector 38 surrounding the male Luer fitting 39 of the body 50, as indicated by the air flow path 70. The valve 20 also has a solid head 22 with a “smiley cut” 26 formed on one side and a top surface 24 that is positioned generally flush with a port 52 of the cavity 51 when the connector 10 is de-activated. The edge of the top surface 24 seals to the port 52. The top surface 24 is continuous, *i.e.* there is no slit or penetration in the surface that may trap bacteria or other contamination. The conventional connector 10 has a representative overall length of L1. In certain conventional valves, L1 = 1.324 inches.

[0016] FIG. 1B depicts the valve 10 in the activated position, *i.e.* a male Luer fitting 2 sealingly coupled to the connector 10 at port 52. The tip of the male Luer fitting 2 has displaced the external surface 24 downward and the applied force has caused the head 22 to buckle toward the smiley cut 26 as well as causing the cylindrical wall 28 to buckle. Two

external dimples 40 (indicated in phantom) are located on an exterior surface (not visible in the cross-section of FIG. 1B) of the wall 28. The dimples 40 control the collapse of the wall 28 to occur at a predictable level of force. In the activated configuration, the primary seal between the shoulder 30 and ridge 54 is opened such that fluid may flow through the connector 10, as indicated by the fluid flow path 80 that passes from the lumen 3 of the male Luer fitting 2 through the cavity 51 and through channels 62 in the base and out through an output flow channel 64 of the male fitting 39 that is fluidly coupled to the flow channel 5 of the connected female Luer fitting 4. Air passes out of the air chamber 32 along the air flow path 70 as the valve 20 collapses.

[0017] While the conventional needleless connector 10 of FIGS. 1A, 1B allows the connection and disconnection of a male Luer fitting and seals the flow path when there is no fitting mated with the connector 10, it is generally desirable to have the least possible amount of fluid contained in the needleless connector. To this end, the disclosed needleless connector 100 provides the same functionality of allowing the connection and disconnection of the same male Luer fitting and sealing of the flow path when there is no fitting mated, with the improvement of a smaller body that results in a smaller internal volume of fluid compared to the conventional connector 10. As a medication that remains trapped in the connector may not reach a patient, unless the connector is flushed with a medical liquid such as a saline solution, reducing the liquid volume of a needleless connector increases the amount of the medication that reaches the patient. In addition, as medications may degrade over time and connectors may not always be flushed after administration of the medication through a needleless connector, a reduction in the trapped volume of a medication in a connector necessarily reduces the amount of degraded medication that may reach the patient at a later time.

[0018] FIGS. 2A-2B are cross-sections of an exemplary needleless connector 100 according to certain aspects of the present disclosure. The connector 100 has a body 150 that defines a cavity 151. The connector 100 has a characteristic length L2, which references the same features as the characteristic length L1, this is less than L1. In certain embodiments, L2 is less than 90% of L1. In certain embodiments, L2 = 1.200 inches. The smaller body 150 contains less fluid than the body 50 of the conventional connector 10. The body 150 of the connector 100 is generally similar to the body 150 of connector, although the port 152 and the male Luer fitting 139 meet the same ISO standards as port 52 and fitting 39 of connector 10. In certain embodiments, the male Luer fitting 139 may be replaced with a tubing

connector (not shown) that accepts an end of a length of tubing, for example when a connector 100 is integrated into an IV set.

[0019] As the size of the connector 100 is reduced compared to connector 10, the volume of the cavity 151 that is external to the valve 120 is also reduced compared to connector 10. As the wall thickness of the body 150 and some internal features must remain the same as body 50, for example to provide a minimum thickness for flow of molten plastic in a molding process, the reduction in the fluid volume may be proportionately greater than the reduction in a linear dimension. In certain embodiments, the reduction in fluid volume may be 40% while the reduction in the linear dimension L2 vs. L1 may be only 10%.

[0020] The connector 100 has a valve 120 disposed within the cavity 151 that is generally similar to the valve 20 of connector 10. The valve 120 comprises a flexible material, for example silicone. Valve 120 has a center axis 101 and a head 122 with two smiley cuts 126, 128 disposed on opposite sides of the head. The details of the smiley cuts are discussed in greater detail in FIGS. 3-5.

[0021] FIGS. 3-5 are cross-sections of various example embodiments of a valve according to certain aspects of the present disclosure. FIG. 3 depicts the head 222 of a valve 200 that is similar to valve 120 of FIG. 2. The valve 200 has two identical smiley cuts 210 that are equally spaced from a center axis 201 of the valve 200 and have a common depth D2. The smiley cuts 210 have a uniform profile, *i.e.* the shape is the same over the length of the smiley cut, through the head 222. In FIG. 3, the directions of length, width, and depth of the smiley cuts are shown by the coordinate legend in FIG. 3, wherein the curved arrow indicates that length “L” is defined as directed into the plane of the drawing. The length of a smiley cut is defined as the value of the uniform profile in the direction of length L as measured at the maximum depth D. In certain embodiments, the depth D2 is defined at the center of the profile. In certain embodiments, the profile is symmetric. In certain embodiments, the profile is not symmetric. In certain embodiments, the profile has a constant radius. In certain embodiments, the profile has a variable radius. In certain embodiments, D2 is less than or equal to 30% of a diameter D1 of the head 222. In certain embodiments, D2 is less than or equal to 25% of D1. In certain embodiments, D1 = 0.150 inches. In certain embodiments, D2 = 0.038 inches.

[0022] FIG. 4 depicts the head 322 of a valve 300 that is similar to valve 120 of FIG. 2. The valve 300 has smiley cuts 310, 315 that are disposed on opposite sides of head 322 with

depths D3, D4 respectively. In certain embodiments, D3 is equal to or greater than 30% of D1 while D4 is less than or equal to 25% of D1. In this example, smiley cut 315 is axially offset along the center axis 301 from smiley cut 310. In this example, the smiley cuts 310, 315 each have a parabolic profile, wherein the profile of smiley cut 310 is not the same profile as smiley cut 315. In certain embodiments, D3 and D4 are equal while smiley cuts 310, 315 have different parabolic profiles such that the respective widths W3, W4 of the smiley cuts 310, 315 are not equal. In certain embodiments W3 and W4 are equal.

[0023] FIG. 5 depicts the head 422 of a valve 400 that is similar to valve 120 of FIG. 2. The valve 400 has smiley cuts 410, 412 that are disposed on opposite sides of head 422. In this example, smiley cuts 410, 412 are axially aligned with different depths D5, D6. In certain embodiments, D5 is equal to or greater than 50% of D1. In certain embodiments, D6 is less than or equal to 20% of D1. In this example, smiley cut 410 has a parabolic profile while smiley cut 412 has a constant radius profile.

[0024] It can be seen that the disclosed embodiments of the needleless connector have a reduced internal volume of fluid while providing a self-sealing connection port of the same size and configuration of a conventional needleless connector. This reduction in fluid volume reduces the amount of fluid that remains trapped in the disclosed needleless connector when a connector attached to an IV line or a container such as a syringe is disconnected from the connector. While some amount of fluid is unavoidably retained in any needleless connector, reducing the amount of fluid that remains trapped in a connector increases the amount of an administered medication that reaches the patient. In addition, as medications may degrade over time, a reduction in the trapped volume of a medication in a connector necessarily reduces the amount of degraded medication that may reach the patient at a later time.

[0025] The previous description is provided to enable any person skilled in the art to practice the various aspects described herein. While the foregoing has described what are considered to be the best mode and/or other examples, it is understood that various modifications to these aspects will be readily apparent to those skilled in the art, and the generic principles defined herein may be applied to other aspects. Thus, the claims are not intended to be limited to the aspects shown herein, but is to be accorded the full scope consistent with the language claims, wherein reference to an element in the singular is not intended to mean "one and only one" unless specifically so stated, but rather "one or more." Unless specifically stated otherwise, the terms "a set" and "some" refer to one or more. Pronouns in the masculine

(e.g., his) include the feminine and neuter gender (e.g., her and its) and vice versa. Headings and subheadings, if any, are used for convenience only and do not limit the invention.

[0026] It is understood that the specific order or hierarchy of steps in the processes disclosed is an illustration of exemplary approaches. Based upon design preferences, it is understood that the specific order or hierarchy of steps in the processes may be rearranged. Some of the steps may be performed simultaneously. The accompanying method claims present elements of the various steps in a sample order, and are not meant to be limited to the specific order or hierarchy presented.

[0027] Terms such as “top,” “bottom,” “front,” “rear” and the like as used in this disclosure should be understood as referring to an arbitrary frame of reference, rather than to the ordinary gravitational frame of reference. Thus, a top surface, a bottom surface, a front surface, and a rear surface may extend upwardly, downwardly, diagonally, or horizontally in a gravitational frame of reference.

[0028] A phrase such as an “aspect” does not imply that such aspect is essential to the subject technology or that such aspect applies to all configurations of the subject technology. A disclosure relating to an aspect may apply to all configurations, or one or more configurations. A phrase such as an aspect may refer to one or more aspects and vice versa. A phrase such as an “embodiment” does not imply that such embodiment is essential to the subject technology or that such embodiment applies to all configurations of the subject technology. A disclosure relating to an embodiment may apply to all embodiments, or one or more embodiments. A phrase such an embodiment may refer to one or more embodiments and vice versa.

[0029] The word “exemplary” is used herein to mean “serving as an example or illustration.” Any aspect or design described herein as “exemplary” is not necessarily to be construed as preferred or advantageous over other aspects or designs.

[0030] All structural and functional equivalents to the elements of the various aspects described throughout this disclosure that are known or later come to be known to those of ordinary skill in the art are expressly incorporated herein by reference and are intended to be encompassed by the claims. Moreover, nothing disclosed herein is intended to be dedicated to the public regardless of whether such disclosure is explicitly recited in the claims. No claim element is to be construed under the provisions of 35 U.S.C. §112, sixth paragraph,

unless the element is expressly recited using the phrase “means for” or, in the case of a method claim, the element is recited using the phrase “step for.” Furthermore, to the extent that the term “include,” “have,” or the like is used in the description or the claims, such term is intended to be inclusive in a manner similar to the term “comprise” as “comprise” is interpreted when employed as a transitional word in a claim.

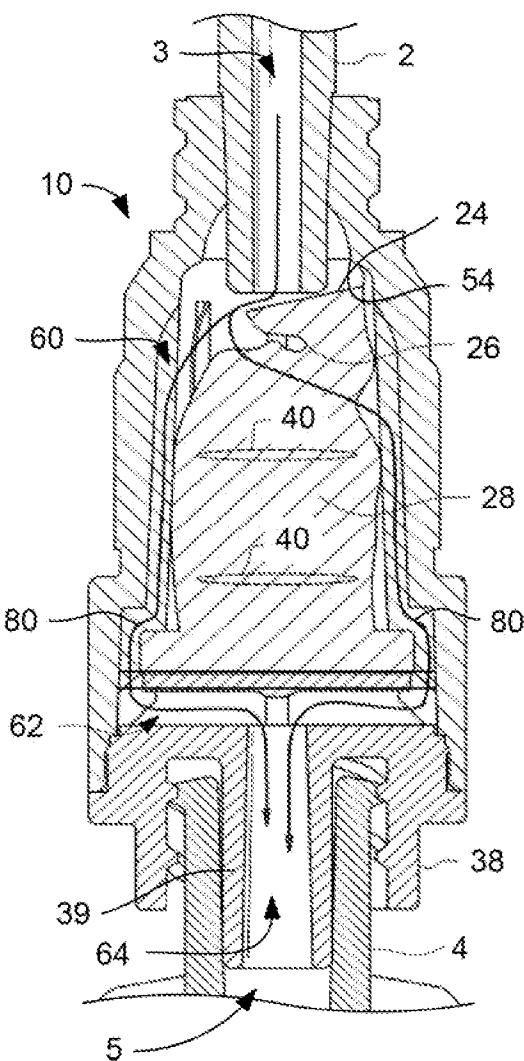
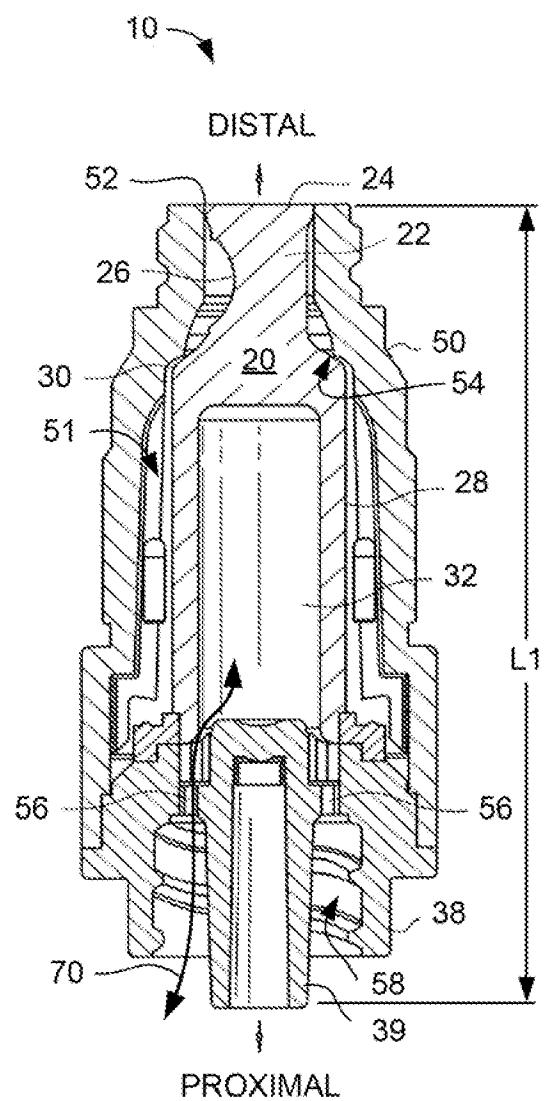
## CLAIMS

What is claimed is:

1. A needleless connector comprising:
  - a body having an internal cavity with a sealing ridge, a port, an output flow channel, and a fluid flow path between the port and output flow channel; and
  - a collapsible valve disposed within the cavity, the valve comprising:
    - a cylindrical wall having a center axis and a shoulder and defining an internal air space, wherein the shoulder is configured to sealingly contact the ridge of the body so as to block the fluid flow path; and
    - a head fixedly attached to the wall, the head having first and second smiley cuts disposed on opposite sides of the head.
2. The needleless connector of claim 1, wherein the first and second smiley cuts have a common width and a common depth.
3. The needleless connector of claim 1, wherein the first smiley cut has a first depth and the second smiley cut has a second depth that is less than the first depth.
4. The needleless connector of claim 1, wherein the first smiley cut has a first width and the second smiley cut has a second width that is less than the first width.
5. The needleless connector of claim 1, wherein the first and second smiley cuts each have a uniform profile through the head.
6. The needleless connector of claim 1, wherein at least one of profiles of the first and second smiley cuts each comprises a constant radius.
7. The needleless connector of claim 1, wherein at least one of profiles of the first and second smiley cuts comprises a variable radius.
8. The needleless connector of claim 1, wherein at least one of profiles of the first and second smiley cuts comprises a parabola.

9. The needleless connector of claim 1, wherein a point of maximum depth of the second smiley cut is axially offset along the center axis from a point of maximum depth of the first smiley cut.
10. A collapsible valve comprising:
  - a cylindrical wall having a center axis and defining an internal air space; and
  - a head fixedly attached to the wall, the head having first and second smiley cuts disposed on opposite sides of the head.
11. The collapsible valve of claim 10, wherein the first and second smiley cuts have a common width and a common depth.
12. The collapsible valve of claim 10, wherein the first smiley cut has a first depth and the second smiley cut has a second depth that is less than the first depth.
13. The collapsible valve of claim 10, wherein the first smiley cut has a first width and the second smiley cut has a second width that is less than the first width.
14. The collapsible valve of claim 10, wherein the first and second smiley cuts each have a uniform profile through the head.
15. The collapsible valve of claim 10, wherein at least one of profiles of the first and second smiley cuts each comprises a constant radius.
16. The collapsible valve of claim 10, wherein at least one of profiles of the first and second smiley cuts comprises a variable radius.
17. The collapsible valve of claim 10, wherein at least one of profiles of the first and second smiley cuts comprises a parabola.
18. The collapsible valve of claim 10, wherein a point of maximum depth of the second smiley cut is axially offset along the center axis from a point of maximum depth of the first smiley cut.

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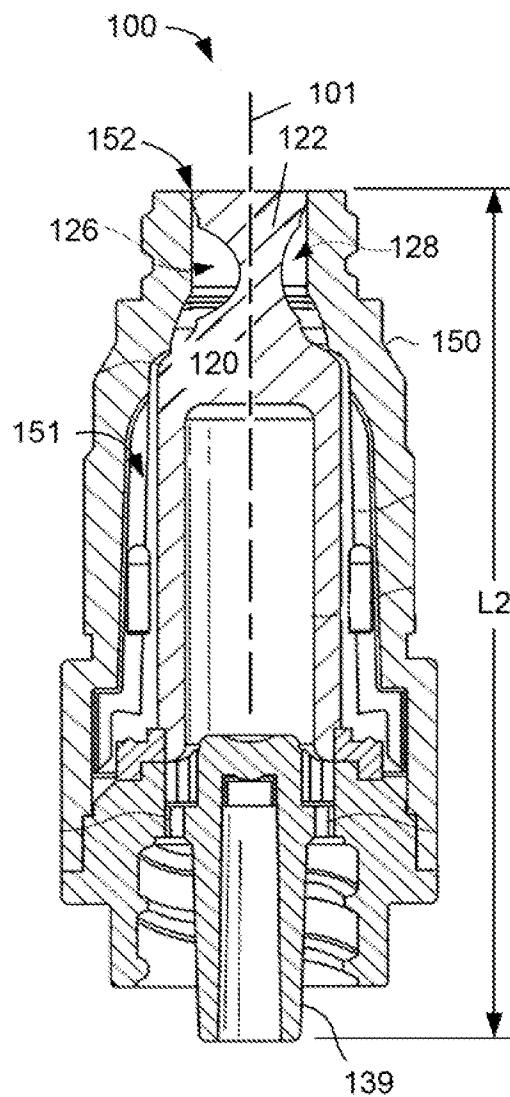


FIG. 2A

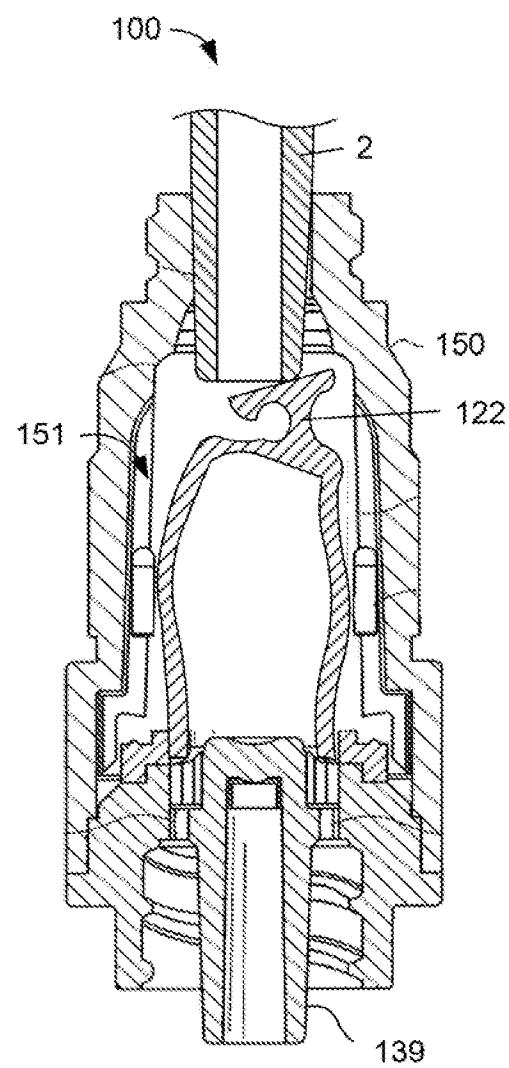


FIG. 2B

3 / 3

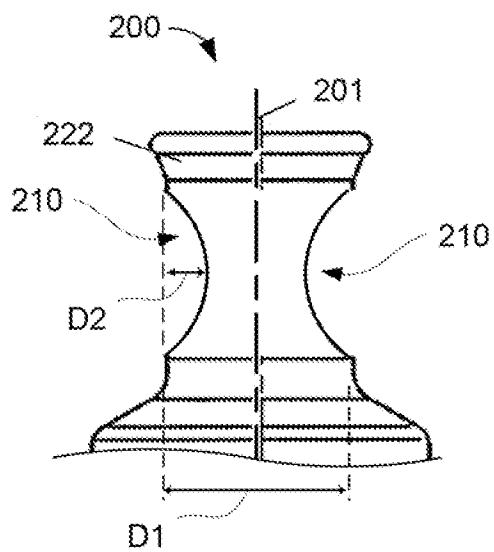


FIG. 3

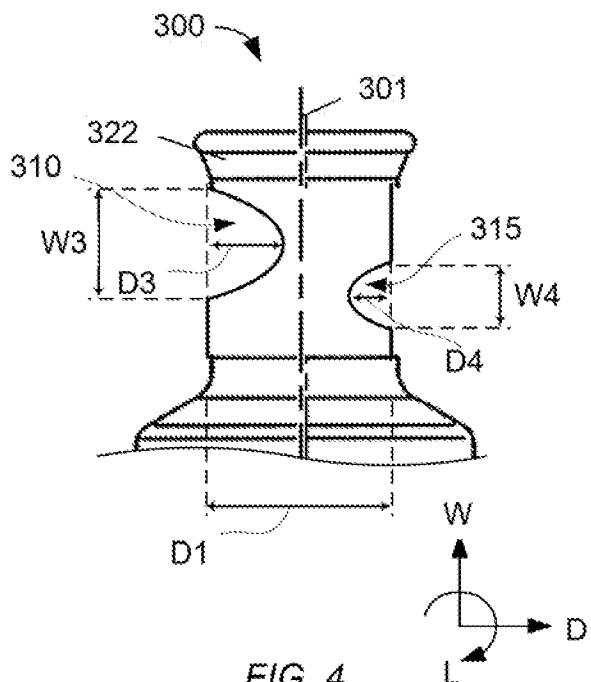


FIG. 4

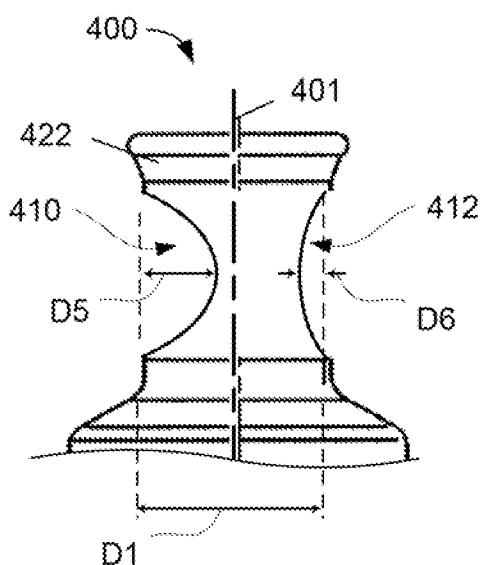


FIG. 5

# INTERNATIONAL SEARCH REPORT

International application No

PCT/US2014/017486

**A. CLASSIFICATION OF SUBJECT MATTER**  
INV. A61M39/26  
ADD.

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)  
A61M

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)

EP0-Internal, WPI Data

**C. 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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X	WO 2013/016077 A2 (CAREFUSION 303 INC [US]; PANIAN TYLER DEVIN [US]; MANSOUR GEORGE [US]) 31 January 2013 (2013-01-31) figure 2B -----	1-18
Y	WO 2011/014265 A1 (MEDEGEN INC [US]; MANSOUR GEORGE M [US]; BENNETT JAMES [US]) 3 February 2011 (2011-02-03) page 6 - page 9; figures 1-3 -----	1-18
Y	WO 2011/060384 A1 (CAREFUSION 303 INC [US]; TRUITT TIM L [US]; MAZZA ALEX T [US]) 19 May 2011 (2011-05-19) figures 2-3 -----	1-18
		-/-

Further documents are listed in the continuation of Box C.

See patent family 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 application or patent 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)
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"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

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
7 May 2014	13/05/2014
Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Authorized officer  Schiopu, D

**INTERNATIONAL SEARCH REPORT**

International application No  
PCT/US2014/017486

**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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**INTERNATIONAL SEARCH REPORT**

Information on patent family members

International application No

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