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TITLE OF THE INVENTION

PREFILLED DISPOSABLE NASAL DRUG DELIVERY DEVICE

FIELD OF THE INVENTION

5 The present invention relates generally to nasal drug delivery devices. Specifically, the invention is directed to a nasal drug delivery device that incorporates a drug container that cannot be refilled post use, preventing possible re-use of the nasal drug delivery device.

10 BACKGROUND OF THE INVENTION

 In many cases, it is not only the cost of a drug that prohibits a treatment from becoming widely accessible but also the cost of packaging. Many companies strive to reduce the cost of proven life-saving treatments so that treatments can be more readily accessible.

 Reducing the cost of traditional packaging is one example of a way to lower the
15 cost of such treatments. Reducing the cost of traditional packaging of drug delivery devices has been an area of focus for some time. The problem with traditional packaging of drug delivery devices is two-fold. The first is the cost of the primary glass drug container. The second is the cost of filling the glass container. Manufacturing and filling, are by their very nature, two distinct processes. Manufacturing involves formation of the container, and subsequent packing
20 and shipping of the container from the manufacturing facility to the filling facility. Filling involves unpacking the container at the filling facility followed by filling of the container with drug.

 An additional problem that plagues conventional drug delivery devices is that conventional drug delivery devices can be refilled and reused. Re-using drug delivery devices
25 contributes to the transmission of communicable diseases like HIV. Thus, there is a need for a low-cost drug delivery device that cannot be refilled or reused.

SUMMARY OF THE INVENTION

 The drug delivery device described herein provides a solution to the problems of
30 traditional drug delivery devices discussed above.

 For the purpose of clarity, orientation references are hereby established for the description of this invention. The term “proximal” refers to a position that is toward the administrator’s body part that provides contact with the device to collapse the drug container,

e.g., a physician's, nurse's or other person's thumb which contacts and depresses the actuator, or a patient's thumb which contacts depresses the actuator. The term "distal" refers to a position that is away from the administrator's body part that provides contact with the device to collapse the drug container, e.g., a physician's, nurse's or other person's thumb which contacts and
5 depresses the actuator, or a patient's thumb which contacts depresses the actuator. During use of the device, the distal end approaches and, and one embodiment of the use of the device, may contact the nostril of the patient. In another embodiment of use of the device, the device may not contact the nostril of the patient. The hand of the person administering the drug to the patient may in fact be the hand of the patient, or it may be the hand of another person administering the
10 drug to the patient.

Described herein are low-cost, pre-filled disposable nasal drug delivery devices that cannot be refilled or re-used post use. The drug delivery device described herein includes a pre-filled drug container that, after use, remains locked in its post-use state. This feature ensures that all of the drug is dispensed from the drug container, and the drug delivery device cannot be
15 refilled or re-used post use. The drug delivery device described herein further provides a solution to the problems of traditional drug delivery devices discussed above as it is made of plastic that is pre-filled during the container's manufacturing process eliminating the use of costly glass containers that need to be shipped and filled.

Described herein is a drug delivery device comprising a drug container
20 comprising at least one bellow, wherein the at least one bellow comprises a first surface and an opposing second surface, wherein the first surface is comprised of a first Belleville spring and the opposing second surface is comprised of a second Belleville spring, wherein the second Belleville spring has a higher spring rate than the first Belleville spring, wherein the drug container is positioned adjacent to a duct and within a body, wherein a duct cover, having a
25 nozzle and a nozzle hole, is movably attached to the body, and wherein the drug container contains a drug.

In certain embodiments of the drug delivery device, the duct cover covers the duct. In certain embodiments of these embodiments, the duct cover has a nozzle base grip that is attached to a body long pin.

30 In certain embodiments of the drug delivery device, the duct cover does not cover the duct. In a further embodiment of this embodiment, the duct cover has a nozzle base grip that is not attached to a body long pin.

In certain embodiments of the drug delivery device, the drug container comprises a series of axially aligned bellows.

In certain embodiments of the drug delivery device, the drug container further comprises a distal end and a proximal end and a top, wherein the top is located at the proximal
5 end of the drug container and is axially aligned with the at least one bellow.

In certain embodiments of the drug delivery device, the drug container further comprises at least one priming bellow.

In certain embodiments of the drug delivery device, the body comprises a pair of
flanges.

10 In certain embodiments of the drug delivery device, the device further comprise an actuator having a proximal end and distal end, wherein the distal end of the actuator engages the proximal end of the drug container. In certain embodiments of these embodiments, the actuator comprises a distal end that is generally convex, and wherein the drug container further
15 comprises a mating proximal end that is generally concave. In alternative embodiments, the actuator comprises a distal end that is generally concave, and wherein the drug container comprises a mating proximal end that is generally convex.

In certain embodiments of the drug delivery device, the actuator is within a chute which surrounds the drug container.

20 In certain embodiments of the drug delivery device, the drug container is collapsed when the actuator rests adjacent the distal end of the drug container.

Also, described herein is a drug delivery device comprising a drug container comprising at least one bellow, wherein the at least one bellow comprises a first surface and an opposing second surface, wherein the first surface is comprised of a first Belleville spring and the opposing second surface is comprised of a second Belleville spring, wherein the second
25 Belleville spring is oriented opposite to the first Belleville spring, wherein the first and second Belleville spring are joined at their common outer edge, and wherein the second Belleville spring has a higher spring rate than the first Belleville spring.

In certain embodiments, the drug container of the drug delivery devices described herein comprises one bellow. In certain embodiments, the drug container of the drug delivery
30 devices described herein comprises a series of axially aligned bellows. The number of axially-aligned bellows of the drug container of the delivery device described herein is limited only by internal volume requirements and by the requirement for the drug container to resist buckling under an axial compressive load. In certain embodiments, the drug container of the drug delivery

devices described herein comprises a series of two axially aligned bellows. In certain embodiments, the drug container of the drug delivery devices described herein comprises a series of two or more axially aligned bellows. In certain embodiments, the drug container of the drug delivery devices described herein comprises a series of three axially aligned bellows. In certain
5 embodiments, the drug container of the drug delivery devices described herein comprises a series of three or more axially aligned bellows. In certain embodiments, the drug container of the drug delivery devices described herein comprises a series of four axially aligned bellows. In certain embodiments, the drug container of the drug delivery devices described herein comprises a series of four or more axially aligned bellows.

10 In certain embodiments, the drug container of the drug delivery devices described herein comprises a series of five axially aligned bellows. In certain embodiments, the drug container of the drug delivery devices described herein comprises a series of five or more axially aligned bellows. In certain embodiments, the drug container of the drug delivery devices described herein comprises a series of six axially aligned bellows. In certain embodiments, the
15 drug container of the drug delivery devices described herein comprises a series of six or more axially aligned bellows. In certain embodiments, the drug container of the drug delivery devices described herein comprises a series of seven axially aligned bellows. In certain embodiments, the drug container of the drug delivery devices described herein comprises a series of seven or more axially aligned bellows. In certain embodiments, the drug container of the drug delivery
20 devices described herein comprises a series of eight axially aligned bellows. In certain embodiments, the drug container of the drug delivery devices described herein comprises a series of eight or more axially aligned bellows.

In certain embodiments, of the drug delivery device described herein, at least one of the bellows is stable in both the expanded state and in the compressed states.

25 The drug container of the drug delivery device described herein has a distal end and a proximal end. In certain embodiments, the arrangement of bellows in a drug container comprising more than one bellow comprises orientation of all of the first Belleville springs in the proximal direction, and orientation of all of the second Belleville springs in the distal direction. Orientation of all of the first Belleville springs in the same direction and all of the second
30 Belleville springs in the opposite direction to the first Belleville springs allows the drug container to compress to its minimum volume with the lowest applied force.

In another embodiment, the arrangement of bellows in a drug container comprising of more than one bellow comprises orientation of all of the first Belleville springs in

the distal direction, and orientation of all of the second Belleville springs in the proximal direction. In certain embodiments, comprising two or more bellows, the second Belleville springs may be situated adjacent to one another, whereby some of the first Belleville springs move in the proximal direction to abut their adjoining second Belleville springs, and whereby
5 some of the first Belleville springs move in the distal direction to abut their adjoining second Belleville springs

In certain embodiments of the drug delivery device described herein, wherein the drug container has one bellow, the drug container further comprises a top at the proximal end of the drug container, wherein the top encloses the proximal end of the drug container, and wherein
10 the top is axially aligned with the bellow. In certain embodiments of the drug delivery device described herein, wherein the drug container has one bellow, the drug container further comprises an outlet port at the distal end, wherein the outlet port at the distal end of the drug container is axially aligned with the bellow. In alternate embodiments of the drug delivery device described herein, the outlet port at the distal end of the drug container is not axially
15 aligned with the bellow.

In certain embodiments of the drug delivery devices described herein, wherein the drug container has a series of axially aligned bellows, the drug container further comprises a top at the proximal end of the drug container, wherein the top encloses the proximal end of the drug container, and wherein the top is axially aligned with the series of bellows. Certain
20 embodiments of the drug container of the drug delivery devices described herein further comprise an outlet port at the distal end of the drug container, wherein the outlet port is axially aligned with the series of bellows. In alternate embodiments of the drug delivery device described herein, the outlet port at the distal end of the drug container is not axially aligned with the series of bellows.

In certain embodiments of the drug delivery device described herein, the drug
25 delivery device further comprises a body to accommodate the drug container. The body has a distal end and a proximal end. In certain embodiments, the body comprises at least one flange. In certain embodiments of the drug delivery device described herein, the body comprises a pair of flanges. In certain embodiments, the body comprises one or more flanges, wherein the flanges
30 are displaced, from the distal end of the housing, a distance that allows the user's fingers to be held between the distal surface of the flanges and the patient's skin to stabilize the device during use. In certain embodiments, the body comprises one or more flanges for secure placement of the

user's fingers while the device is being used. In certain embodiments, the flanges may be fully closed. In certain embodiments, the flanges may be partially closed.

In certain embodiments, at the distal end of the drug container, the drug container comprises an integrally molded frangible seal. In other embodiments, at the distal end of the drug container, the drug container comprises a twist-off tab, wherein when the tab is removed. Subsequent to tab removal, the duct cover is rotated to cover the duct and to clip the nozzle base grip to a long pin. Depression of the accutaor results in drug exiting the drug container and flowing through the duct, outlet port, nozzle and nozzle hole and into the nostril.

In certain embodiments, the drug container of the drug delivery devices described herein contains a drug product. In a preferred embodiment, the drug container is pre-filled with the drug product.

Also described herein is a drug delivery device comprising a drug container comprising a top and at least one bellow axially aligned with the top, wherein the at least one bellow comprises a first surface and an opposing second surface, wherein the first surface is comprised of a first Belleville spring and the second opposing surface is comprised of a second, opposing Belleville spring, wherein the second Belleville spring has a higher spring rate than the first Belleville spring, and an outlet port at the distal end of the drug container, wherein the outlet port at the distal end of the drug container is axially aligned with the at least one bellow; a housing, wherein the housing extends between distal and proximal ends, wherein the proximal end is open to receive the drug container, wherein the distal end is open to receive the distal end of the drug container; and a drug product contained within the drug container.

In alternate embodiments of the drug delivery device described herein, the outlet port at the distal end of the drug container is not axially aligned with any bellows.

The drug delivery device can be positioned to be inserted into the patient's nostril for subsequent nasal injection of drug into the nostril.

In certain embodiments, the drug delivery device described herein has a pre-injection position or first position and a post-injection position or second position. In the first position, the drug container is extended axially to its full length, wherein the at least one bellow is expanded, wherein the volume contained within the drug container is maximized. In the second position, the drug container is compressed axially to its minimum length, wherein the at least one bellow is compressed, wherein the volume contained within the drug container is minimized.

With regard to the drug delivery devices described herein, there is no feature on the proximal end of the drug container to which a tensile force can be applied, whereby the drug container can be expanded from the second position back to the first position. In certain embodiments when the drug delivery devices described herein are in the second position, the drug delivery device has dispensed the drug product. In this position the delivery device cannot be refilled or reused.

In certain embodiments, the top of the drug container extends beyond the proximal end of the body when the drug container is in its second position, whereby access to the top of the drug container is ensured. In an alternate embodiment, the top of the drug container is recessed slightly into the proximal end of the body when the drug container is in its second position, but whereby access for the application of force to the top of the drug container can still occur. In certain embodiments when the drug containers described herein are in the second position the drug delivery device has dispensed the drug product. In this position the delivery device cannot be refilled or reused.

In certain embodiments the drug delivery device described herein further comprises a body and an actuator, wherein the distal end of the actuator is in contact with the top of the drug container, and wherein the proximal end of the actuator extends out of the proximal end of the body, whereby applying a force in the distal direction to the proximal end of the actuator compresses the drug container. In certain embodiments, the actuator comprises a means wherein the actuator cannot move in the proximal direction within the body once the actuator has fully compressed the drug container. In a certain embodiments, the proximal end of the actuator extends beyond the proximal end of the body for the entire range of movement of the drug container. In other embodiments, the body comprises one or more flanges, whereby the flanges interact with the user's fingers for stabilizing the device during use. In certain embodiments, the actuator comprises a retention feature that interacts with the body to prevent it from being removed from the body at its maximum extension in the proximal direction.

In certain embodiments, the body comprises an axial length that is a small fraction of the length of the drug container in its second, or compressed, position. In certain embodiments, the body comprises one or more features that interact with mating features of the drug container to retain the distal end of the drug container in the body.

In certain embodiments, less than 100% of the internal volume of the drug container is filled with the drug to be dispensed. The remaining fraction of the volume may be filled with air or another fluid that is not part of the therapy. This fraction must be expelled from

the device before the device is used to dispense the drug to the patient, in an activity called priming. To enable priming, a means for partially compressing the drug container may be employed. In certain embodiments, wherein the drug container comprises two or more bellows, a fraction of those bellows can be designed to change state from the first position to the second position before the remaining bellows change state when the drug container is compressed. The priming bellows would comprise geometry that would cause them to change state under a lower applied force than the remaining bellows. The size and number of priming bellows would be selected so that the change in volume of these bellows, as they move from the first position to the second position, would be greater than the maximum volume to be expelled during priming. In a certain embodiments, one or more priming bellows are configured to be bistable, whereby they do not expand after being compressed

Also described herein are methods of manufacturing the drug containers and the drug delivery devices described herein. In certain embodiments, the drug container is made using blow-fill-seal technology. In another embodiment, the drug container is made using form-fill-seal technology.

BRIEF DESCRIPTION OF THE FIGURES

The foregoing and other features and advantages of the invention will be apparent from the following, more particular description of a preferred embodiment of the invention, as illustrated in the accompanying drawings wherein like reference numbers generally indicate identical, functionally similar, and/or structurally similar elements.

FIGURE 1 is a detail view of an embodiment of the device comprising, in its open-pre-injection position, or first position.

FIGURE 2 is a detail view of an embodiment of the device comprising, in its closed-pre-injection position, or second position.

FIGURE 3 is a perspective view of a bellow of an embodiment of the drug delivery device described herein, in its pre-injection position or first position.

FIGURE 4 is a partial, cross-sectional view of a bellow of an embodiment of the drug delivery device described herein, in its pre-injection position or first position.

FIGURE 5 is a detail view of an embodiment of the device comprising, in its closed-post-injection position, or third position.

FIGURE 6 is a perspective view of an embodiment of the drug container attached to an embodiment of the duct.

FIGURE 7 is a perspective view of an embodiment of the duct.

FIGURE 8 is a perspective view of an embodiment of the actuator.

FIGURE 9 is a detail view of the distal end of a drug container, and a frangible seal employing a twist-off tab.

5 FIGURE 10 is a perspective view of an embodiment of the body half.

FIGURE 11 is a perspective view of an embodiment of the cover.

DETAILED DESCRIPTION OF THE INVENTION

10 The following terms and phrases used herein are defined as follows unless otherwise noted:

“Bellow” means a flexible structure whose volume can be changed by compression or expansion.

15 With regard to the bellows contained in the drug delivery device described herein, when an axial tensile force is applied to a bellow, the Belleville springs are pulled apart. In this position, the bellow is expanded and the volume contained within the bellow is maximized.

20 When an axial compressive force is applied to the bellow, the Belleville springs are forced together such that their opposing internal surfaces abut each other. The first Belleville spring is softer and is proportioned such that when it is compressed, it passes through the neutral position into a second stable position where it abuts the second Belleville spring. The second stable position is a mirror image of the first, expanded position. Due to the relative spring rates and selected geometries, when an axial compressive load is applied to this set of Belleville springs, the second, stiffer, spring remains relatively static and the first, softer, spring deflects. When it is fully deflected into the second position, the bellow is compressed and volume contained within the bellow is minimized.

25 “Belleville spring” means a type of spring shaped like a washer that is three dimensional, wherein the inner diameter resides in a plane which is above the outer diameter’s plane i.e. a frusto-conical shape, which gives the washer a spring characteristic. Belleville spring, disc spring, Belleville washer, conical compression washer, are all names for the same type of spring.

30 “Spring rate” or spring constant, is the relationship between the degree of deflection of a spring and the spring force generated in response to this deflection.

One of the key features of the drug delivery device described herein is that it contains a drug container that is comprised of at least one bellow with unique geometry

comprising two opposing Belleville spring. This unique geometry prevents the drug container from restoring itself to its original or post-injection state once the drug product loaded into the container has been dispensed. This precludes the possibility of the drug delivery device from being refilled or re-used. This unique geometry also allows the drug container to have minimum residual volume when collapsed post-use, allowing the drug loaded into the drug container to be completely dispensed leaving no residual, wasted drug product in the container.

The drug delivery device described herein includes a drug container comprising at least one bellow that has a first surface and a second surface. The surfaces are formed by two opposing Belleville springs, a first Belleville spring forming the first surface and a second Belleville spring forming the second surface. The second Belleville spring is stiffer and has a higher spring rate than the first Belleville spring. The first Belleville spring is softer and is proportioned such that when it is compressed into the flat state, it snaps through the flat position into a second stable position. This second stable position is a mirror image of the initial, unstressed position. Due to the relative spring rates and selected geometries, when an axial load is applied to this set of Belleville springs, the second and stiffer spring remains relatively static, the first, softer spring begins to deflect. When it is deflected into its flat position it snaps through this position and becomes inverted.

This behavior produces two distinct benefits. First, as the first Belleville spring is now inverted and is nesting inside of the stiffer second Belleville spring, the residual volume of the bellow is a small fraction of the initial volume of the bellow when the bellow was in its original or starting position. Second, since the inverted state of the first Belleville spring is also stable, there is no restoring force. Because of this, there is no concern for “suck back” of the delivered drug product. Additionally, since there is no restoring force, the device cannot be refilled and reused.

By way of contrast, with conventional bellows the convolutions are mirror images, identical on either side of the fold or corrugation. Although conventional bellows can compress when an axial load is applied, the residual volume is substantial, and the bellows will recover to its initial geometry when the axial load is released. If conventional bellows were to be used in conjunction with a drug container for a drug delivery device, the substantial residual volume could contribute to a costly amount of unused drug product left in the device. Additionally, as conventional bellows return to its uncompressed state there is a risk of creating a vacuum which can lead to “suck-back” of drug product and under dosing. Also, because conventional bellows can easily return to their uncompressed state and create a vacuum, there is

a possibility that the drug delivery device can be refilled and reused which can contribute to the spread of infectious diseases.

The following terms and phrases used herein are defined as follows unless otherwise noted:

5 “Bellow” means a flexible structure whose volume can be changed by compression or expansion. With regard to the bellows contained in the drug delivery device described herein, when an axial tensile force is applied to a bellow, the Belleville springs are pulled apart. In this position, the bellow is expanded and the volume contained within the bellow is maximized. When an axial compressive force is applied to the bellow, the Belleville springs
10 are forced together such that their opposing internal surfaces abut each other. The first Belleville spring is softer and is proportioned such that when it is compressed, it passes through the neutral position into a second stable position where it abuts the second Belleville spring. The second stable position is a mirror image of the first, expanded position. Due to the relative spring rates and selected geometries, when an axial compressive load is applied to this set of
15 Belleville springs, the second, stiffer, spring remains relatively static and the first, softer, spring deflects. When it is fully deflected into the second position, the bellow is compressed and volume contained within the bellow is minimized.

 “Belleville spring” means a type of spring shaped like a washer that is three dimensional, wherein the inner diameter resides in a plane which is above the outer diameter’s
20 plane i.e. a frusto-conical shape, which gives the washer a spring characteristic. Belleville spring, disc spring, Belleville washer, conical compression washer, are all names for the same type of spring.

 “Spring rate” or spring constant, is the relationship between the degree of deflection of a spring and the spring force generated in response to this deflection.

25 One of the key features of the drug delivery device described herein is that it contains a drug container that is comprised of at least one bellow with unique geometry comprising two opposing Belleville springs. This unique geometry prevents the drug container from restoring itself to its original or post-injection state once the drug product loaded into the container has been dispensed. This precludes the possibility of the drug delivery device from
30 being refilled or re-used. This unique geometry also allows the drug container to have minimum residual volume when collapsed post-use, allowing the drug loaded into the drug container to be completely dispensed leaving no residual, wasted drug product in the container.

The drug delivery device described herein includes a drug container comprising at least one bellow that has a first surface and a second surface. The surfaces are formed by two opposing Belleville springs, a first Belleville spring forming the first surface and a second Belleville spring forming the second surface. The second Belleville spring is stiffer and has a higher spring rate than the first Belleville spring. The first Belleville spring is softer and is proportioned such that when it is compressed into the flat state, it snaps through the flat position into a second stable position. This second stable position is a mirror image of the initial, unstressed position. Due to the relative spring rates and selected geometries, when an axial load is applied to this set of Belleville springs, the second and stiffer spring remains relatively static, the first, softer spring begins to deflect. When it is deflected into its flat position it snaps through this position and becomes inverted.

This behavior produces two distinct benefits. First, as the first Belleville spring is now inverted and is nesting inside of the stiffer second Belleville spring, the residual volume of the bellow is a small fraction of the initial volume of the bellow when the bellow was in its original or starting position. Second, since the inverted state of the first Belleville spring is also stable, there is no restoring force. Because of this, there is no concern for “suck back” of the delivered drug product. Additionally, since there is no restoring force, the device cannot be refilled and reused.

By way of contrast, with conventional bellows the convolutions are mirror images, identical on either side of the fold or corrugation. Although conventional bellows can compress when an axial load is applied, the residual volume is substantial, and the bellows will recover to its initial geometry when the axial load is released. If conventional bellows were to be used in conjunction with a drug container for a drug delivery device, the substantial residual volume could contribute to a costly amount of unused drug product left in the device.

Additionally, as conventional bellows return to its uncompressed state there is a risk of creating a vacuum which can lead to “suck-back” of drug product and under dosing. Also, because conventional bellows can easily return to their uncompressed state and create a vacuum, there is a possibility that the drug delivery device can be refilled and reused which can contribute to the spread of infectious diseases.

Referring to the figures, wherein like reference numerals designate like elements throughout the drawings, FIGURE 1 shows an embodiment of the drug delivery device described herein, in its open-pre-injection position, or first position. The embodiment of the drug delivery device shown in FIGURE 1 has a drug container 10 comprising a series of axially aligned

bellows, specifically four axially aligned bellows, wherein bellows 12 have a first surface 14 and a second surface 16. In other embodiments of the drug delivery device described herein, the drug container can have any number of bellows. In certain embodiments of the drug delivery device described herein, the drug container can have up to twenty, up to fifteen or up to twelve, axially aligned bellows. In certain embodiments of the drug delivery device described herein, the drug container can have two, three, five, six, seven, eight, nine, ten, eleven or twelve axially aligned bellows. First surface 14 is in the shape of a first Belleville spring and second surface 16 is in the shape of a second Belleville spring. The drug delivery device shown in FIGURE 1 has a distal end and a proximal end. As shown in FIGURE 1, drug container 10 has a top 20 located at the distal end of drug container 10 and an outlet port 15 located at the proximal end of drug container 10. Body 17 has flanges 21 and chute 97. Actuator 22 is attached to top 20 resting inside chute 97. Duct cover 88 is movably attached to long pin 91A. Nozzle base grip 30 rests in an open position that is not engaged with long pin 91B. Long pin 91A extends through nozzle base hole 29 (FIGURE 11) and into long pin hole 94 (FIGURE 10).

FIGURE 2 is a detail view of an embodiment of the drug delivery device comprising, in its closed-pre-injection position, or second position. Nozzle base grip 30 is coupled to long pin 91B. Long pin 91B extends through nozzle base grip 30 and into long pin hole 94 (FIGURE 10).

The description of the relationship between body 17 and duct cover 88 depicted in FIGURES 1 and 2 recognizes the different functions of long pins 91 in the delivery device assembly by assigning identifiers 91 A and 91B to the two long pins depicted in FIGURES 1 and 2, such that one of 91A and 91B, e.g., 91A, serves long pin function extending through nozzle base hole 29, whereby duct cover 88 is movably attached to long pin 91, as depicted in FIGURE 1, and one of 91A and 91B, e.g., 91B, serves long pin function extending through nozzle base grip 30, whereby nozzle base grip 30 is coupled to long pin 91, as depicted in FIGURE 2. In one embodiment, 91A serves long pin function extending through nozzle base hole 29, whereby duct cover 88 is movably attached to long pin 91A, and 91B serves long pin function extending through nozzle base grip 30, whereby nozzle base grip 30 is coupled to long pin 91B.

FIGURE 3 shows a perspective view of a bellow of an embodiment of a drug container of the delivery device described herein, in its pre-injection position or first position. FIGURE 3 shows a bellow 12, wherein the bellow has a first surface 14 and a second surface 16. The first surface 14 is in the shape of a first Belleville spring 18 and the second surface 16 is in the shape of a second Belleville spring 19. The second Belleville spring 19 remains stationary

when an axially compressive force is applied to the bellow. The first Belleville spring 18 is capable of deflecting and folding onto the second Belleville spring 19 when an axially compressive force is applied to the bellow.

FIGURE 4 shows a partial cross-sectional view of a bellow of an embodiment of the drug delivery device described herein, in its pre-injection position or first position. FIGURE 4 shows a bellow 12, wherein the bellow has a first surface 14 and a second surface 16.

FIGURE 5 shows a detail view of an embodiment of the device comprising, in its closed-post-injection position, or third position. Drug container 10 is collapsed and actuator 22 is attached to top 20. When the drug delivery device described herein is in the post-injection position, the drug container top 20 is substantially flush with the body 17. Body 17 has a pair of flanges 21. In FIGURE 5, an axial force has been applied to top 20. As shown in FIGURE 5, there is minimal residual space remaining in the drug container 10, thus ensuring that entire amount of drug that was in the drug container 10 in its pre-injection position or first position has been dispensed. Additionally, when compressed in the post injection position, the drug container 10 is stable and requires an equal but opposite axial force to expand back to its post-injection or first position. This prevents the drug delivery device from being reused or refilled. Also shown in FIGURE 5 is housing body 17. The body 17 has a pair of flanges 21.

FIGURE 6 shows a perspective view of an embodiment of the drug container 10 attached to duct 87. Outlet port 15 is axially aligned with bellow 12. Top 20 is axially aligned with bellow 12.

FIGURE 7 is a perspective view of an embodiment of duct 87 with securing tab 90 having securing tab hole 86. Duct 87 has Luer taper 44.

FIGURE 8 is a perspective view of an embodiment of actuator 22.

FIGURE 9 is a detail perspective view of the distal end 36 of the drug container 10. The drug container 10 comprises an outlet port 15. Outlet port 15 has a Luer taper 44 for connecting needle to the drug container 10. In FIGURE 9, drug container 10 is manufactured with an integrally molded, twist-off tab 46 at its distal end 36. Removal of said tab 46 opens the distal end 36 of the drug container 10 for dispensing of the drug contained within drug container 10.

In certain embodiments, when tab 46 is removed a needle hub has access to appropriate geometry for attachment of a needle with a mating Luer geometry. In another embodiment, a film or foil seal can be removed from the opening on the drug container's distal end for dispensing of the drug. In another embodiment, the distal end of the drug container can

be pierced by an extension of the needle in the proximal direction, so that the needle pierces the distal end of the drug container when it is secured to the drug container. In an alternate embodiment, the distal end of the drug container is manually pierced or cut off by the user prior to use. In certain alternate embodiments, the drug delivery device described herein further comprises a needle in communication with the outlet port of the drug container.

FIGURE 10 is a perspective view of an embodiment of body half 23 having long pin 91, long pin hole 94, short pin 92, short pin hole 93, body half flange 95, and body half chute 96. A first body half 23 associates with a second body half 23 by inserting long pin 91 of the first body half 23 into long pin hole 94 of the second body half 23 and short pin 92 of the first body half 23 into short pin hole 93 of the second body half 23 and contacting body half chute 96 of the first body half 23 with body half chute 96 of the second body half 23 to form body 17 shown in FIGURE 1 having chute 97 and flanges 21.

FIGURE 11 is a perspective view of an embodiment of duct cover 88 having nozzle 25, nozzle base 26, stretchable nozzle base 28, nozzle base hole 29, and nozzle base grip 30. Nozzle 25 has nozzle hole 31. Stretchable nozzle base 28 retains flexibility enabling nozzle 25 to cover outlet 15 shown in FIGURE 1 and nozzle base grip 30 to attach to long pin 91B shown in FIGURE 1 following pivotal rotation of duct cover 88 around long pin 91A of FIGURE 1.

The drug delivery device can be used to deliver any type of drug product that can be delivered via nasal delivery. In certain embodiments of the drug delivery device described herein, the drug in the drug container may comprise one or more of the following: human papillomavirus quadrivalent vaccine, recombinant; human papillomavirus 9-valent vaccine, recombinant; haemophilus B conjugate vaccine or meningococcal protein conjugate; hepatitis B vaccine, recombinant; haemophilus B conjugate; hepatitis B (recombinant) vaccine; hepatitis A vaccine, inactivated; pneumococcal vaccine polyvalent; artemether; cyclimorph (morphine and cyclizine); cyclizine; morphine; codeine; chlorphenamine; fosphenytoin sodium; chlorpromazine; haloperidol; epinephrine; hydroxocobalamin; heparin sodium; phytomenadione; atropine; furosemide; lidocaine; dalteparin sodium; digoxin; amiodarone; dextran 70; polygeline; hyoscine hydrobromide; oxytocin and ergometrine; oxytocin; carbetocin; magnesium sulfate; dexamethasone; metoclopramide; ondansetron; ketamine; neostigmine; pyridostigmine; dimercaprol; ranitidine; testosterone; calcium gluconate; diazepam; acetylcysteine; sulfamethoxazole + trimethoprim; hydroxocobalamin; protamine sulfate; tranexamic acid; verapamil; anti-D immunoglobulin (human); diphtheria antitoxin; suxamethonium; fluphenazine;

salbutamol; pediatric hexavalent combination vaccine for haemophilus influenzae type B conjugate, recombinant hepatitis B surface antigen, diphtheria, tetanus, 5-component acellular pertussis, and inactivated poliovirus Types 1, 2, and 3; BCG Vaccine; cholera vaccine; diphtheria vaccine; haemophilus influenzae type B vaccine; influenza vaccine; Japanese
5 encephalitis vaccine; measles vaccine; meningococcal meningitis vaccine; mumps vaccine; pertussis vaccine; pneumococcal vaccine; poliomyelitis vaccine; rabies vaccine; rotavirus vaccine; rubella vaccine; tetanus vaccine; typhoid vaccine; varicella vaccine; yellow fever vaccine. In certain embodiments of the drug delivery device described herein, the drug container is pre-filled with a drug such as oxytocin or carbetocin.

10 The drug container may be produced using a variety of manufacturing methods. In certain embodiments, the drug container is manufactured by blow-fill-seal technology (BFS). In other embodiments, the drug container is manufactured by form-fill-seal technology (FFS). In preferred embodiments, the drug container is made of thin flexible plastic. The drug container and housing of the delivery devices described herein are preferably made of a biocompatible,
15 non-biodegradable polymer. Suitable biocompatible, non-biodegradable polymers include but are not limited to, a polyacrylate; a polymer of ethylene-vinyl acetate; an acyl-substituted cellulose acetate; a non-degradable polyurethane; a polystyrene; a polyvinyl chloride; a polyvinyl fluoride; a poly(vinyl imidazole); a chlorosulphonate polyolefin; a polyethylene oxide; a polyethylene; a polypropylene; a metallocene plastomer, a thermoplastic elastomer, an acrylic,
20 a polycarbonate, an acrylonitrile-butadiene-styrene, a multi-layer barrier film; or a blend, combination, or copolymer thereof. Each component of the drug delivery device described herein can be made of the same or different biocompatible, non-biodegradable polymer. In certain embodiments, a multi-layer barrier film may be used, depending on drug container performance requirements. It should be obvious to those skilled in the art that most of these
25 alternate embodiments may be combined to create a drug container with desired attributes suitable for specific applications.

 The embodiments illustrated and discussed in this specification are intended only to teach those skilled in the art the best way known to the inventors to make and use the invention. Nothing in this specification should be considered as limiting the scope of the present
30 invention. All drawings presented are representative and non-limiting. The above-described embodiments of the invention may be modified or varied, without departing from the invention, as appreciated by those skilled in the art in light of the above teachings. It is therefore to be

understood that, within the scope of the claims and their equivalents, the invention may be practiced otherwise than as specifically described.

WHAT IS CLAIMED IS:

1. A drug delivery device comprising: a drug container comprising at least one
5 bellow, wherein in the at least one bellow comprises a first surface and an opposing second
surface, wherein the first surface is comprised of a first Belleville spring and the opposing
second surface is comprised of a second Belleville spring, wherein the second Belleville spring
has a higher spring rate than the first Belleville spring, wherein the drug container is positioned
adjacent to a duct and within a body, wherein a duct cover, having a nozzle and a nozzle hole, is
10 movably attached to the body, and wherein the drug container contains a drug.
2. The drug delivery device of claim 1 wherein the duct cover covers the duct.
3. The drug delivery device of claim 1 wherein the duct cover does not cover the
15 duct.
4. The drug delivery device of claim 2, wherein the duct cover has a nozzle base
grip that is attached to a body long pin.
5. The drug delivery device of claim 3, wherein the duct cover has a nozzle base
20 grip that is not attached to a body long pin.
6. The drug delivery device of claim 1, wherein the drug container comprises a
series of axially aligned bellows.
25
7. The drug delivery device of claim 6, wherein the drug container further
comprises a distal end and a proximal end and a top, wherein the top is located at the proximal
end of the drug container and is axially aligned with the at least one bellow.
8. The drug delivery device of claim 7, wherein the drug container further
30 comprises at least one priming bellow.

9. The drug delivery device of claim 8, wherein the body comprises a pair of flanges.

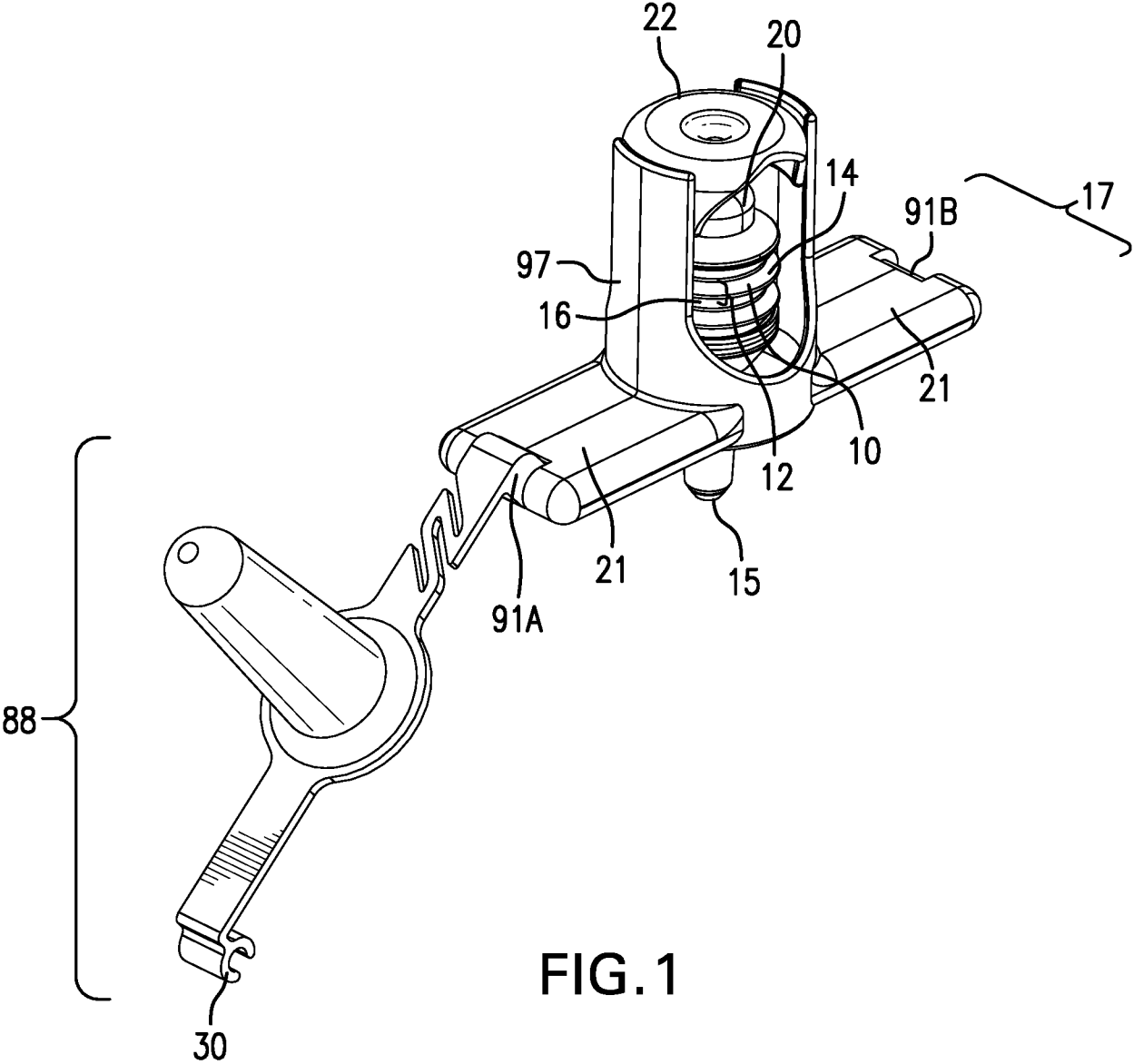
5 10. The drug delivery device of claim 9, further comprising an actuator having a proximal end and distal end, wherein the distal end of the actuator engages the proximal end of the drug container.

10 11. The drug delivery device of claim 10, wherein the actuator comprises a distal end that is generally convex, and wherein the drug container further comprises a mating proximal end that is generally concave.

15 12. The drug delivery device of claim 10, wherein the actuator comprises a distal end that is generally concave, and wherein the drug container comprises a mating proximal end that is generally convex.

13. The drug delivery device of claim 10, wherein the actuator is within a chute which surrounds the drug container.

20 14. The drug delivery device of claim 13, wherein the drug container is collapsed when the actuator rests adjacent the distal end of the drug container.



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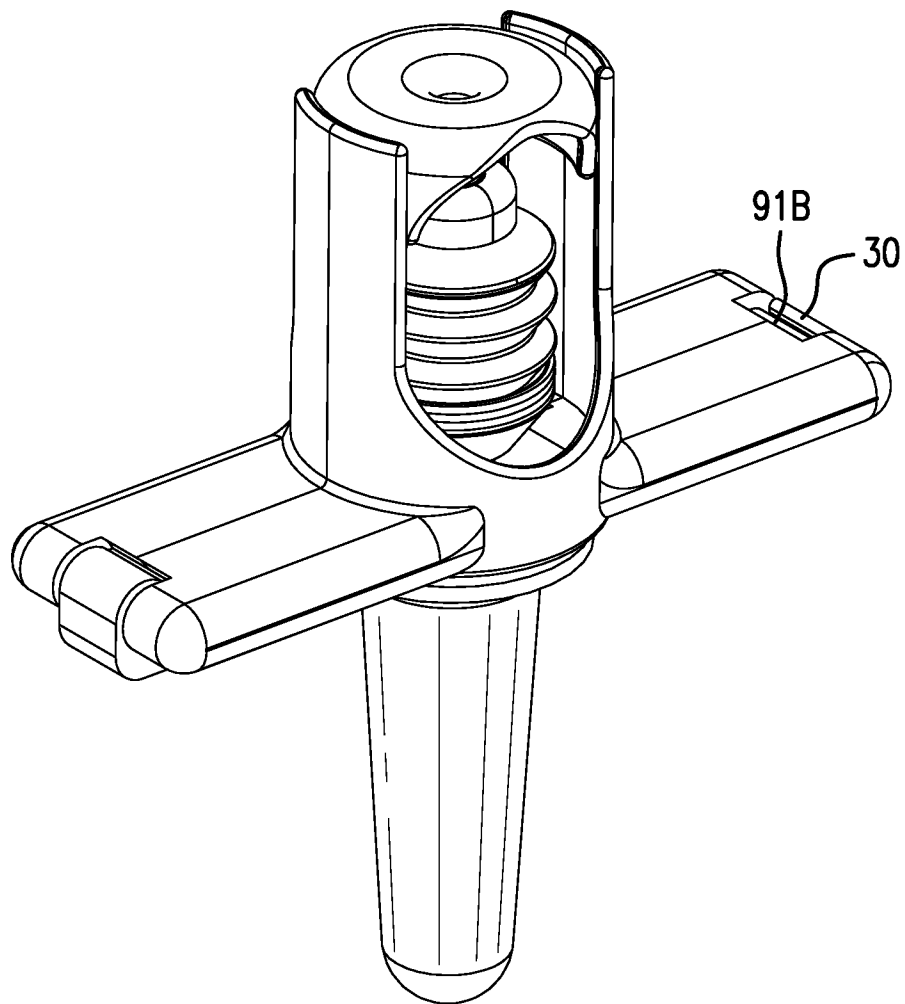


FIG. 2

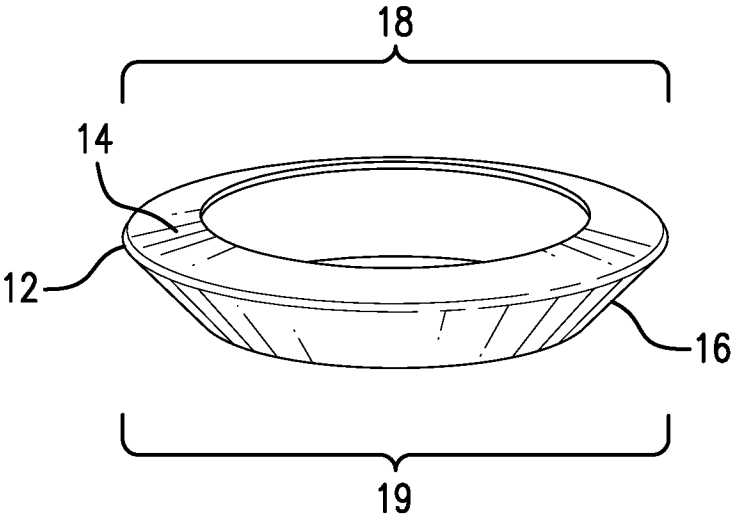


FIG.3

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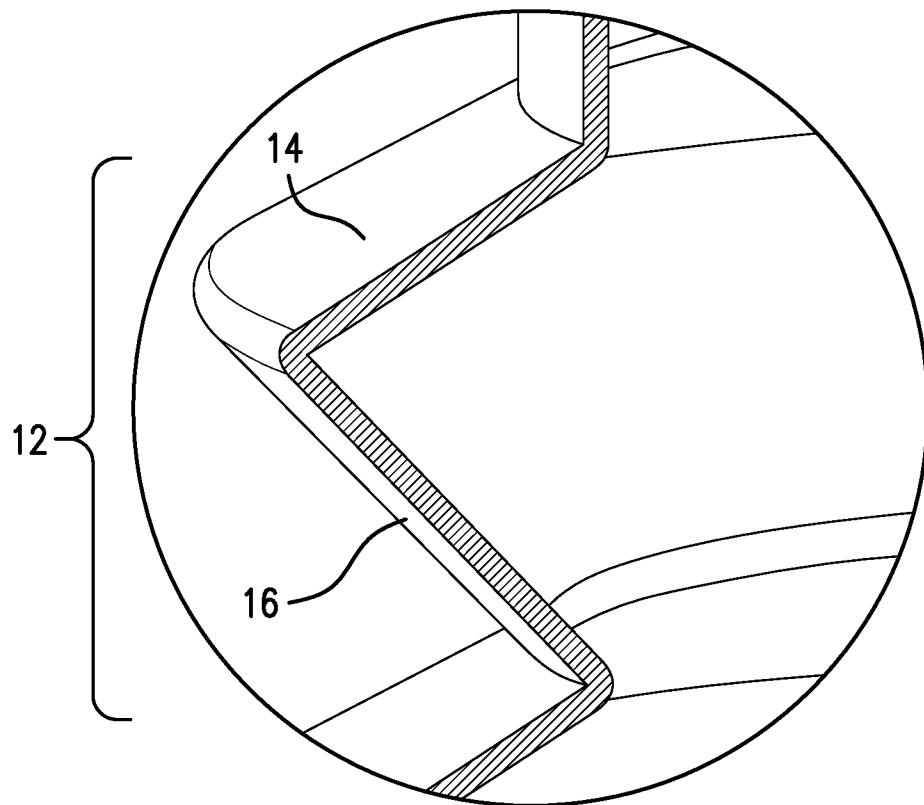


FIG. 4

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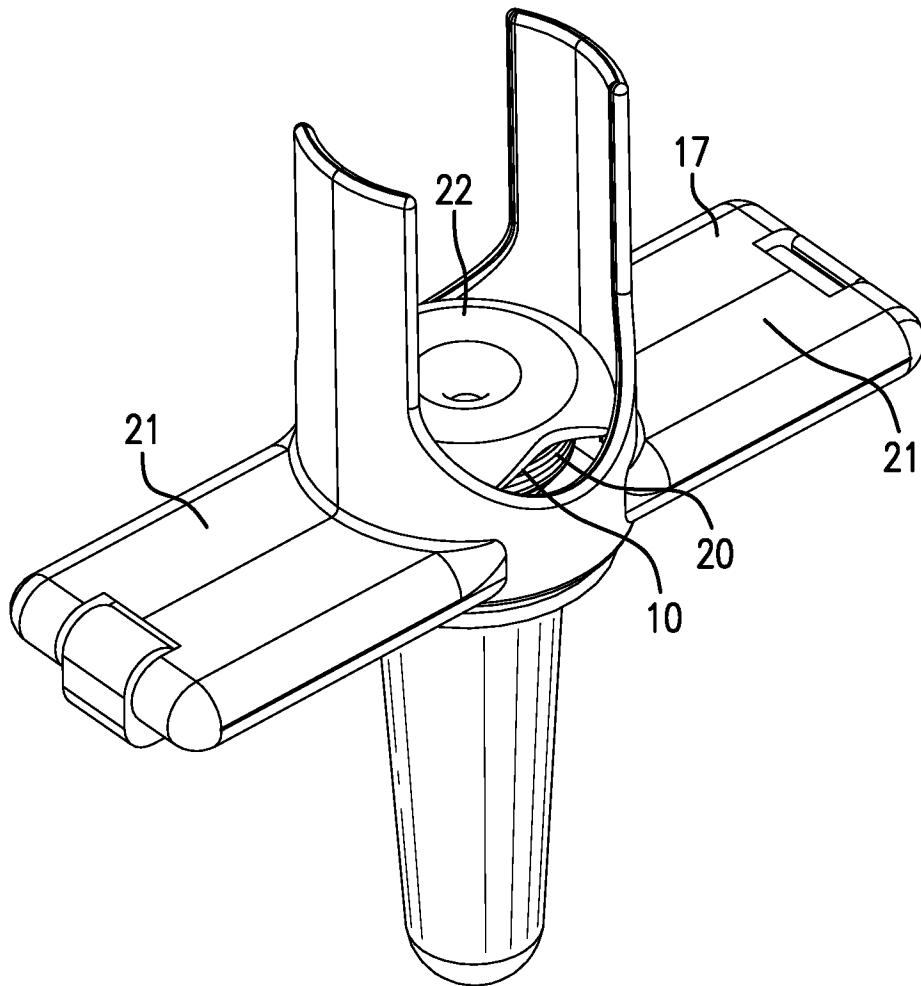


FIG. 5

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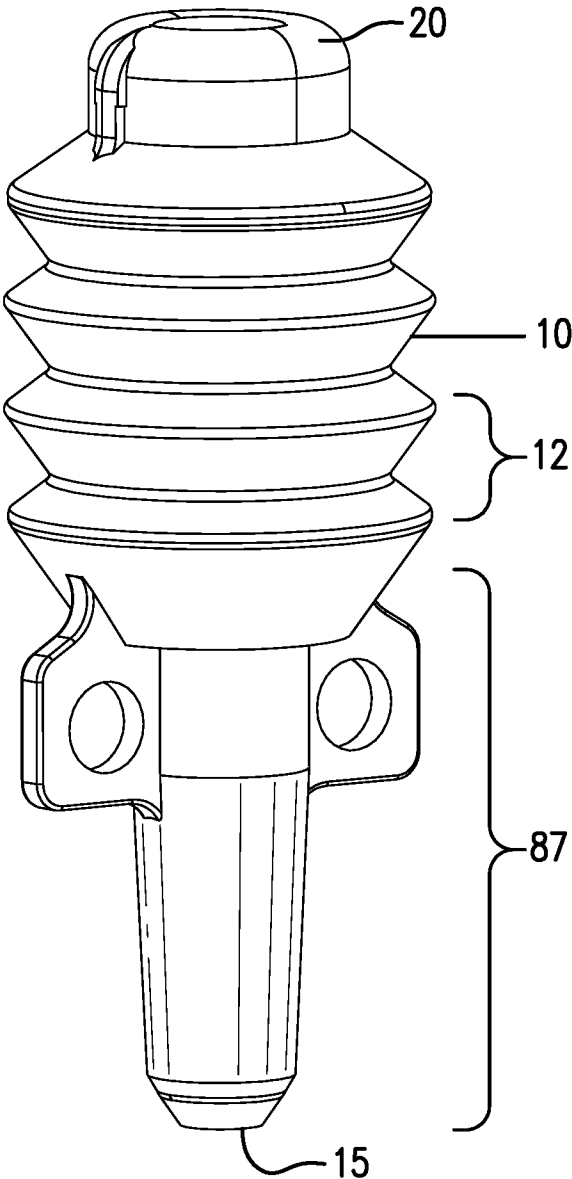


FIG.6

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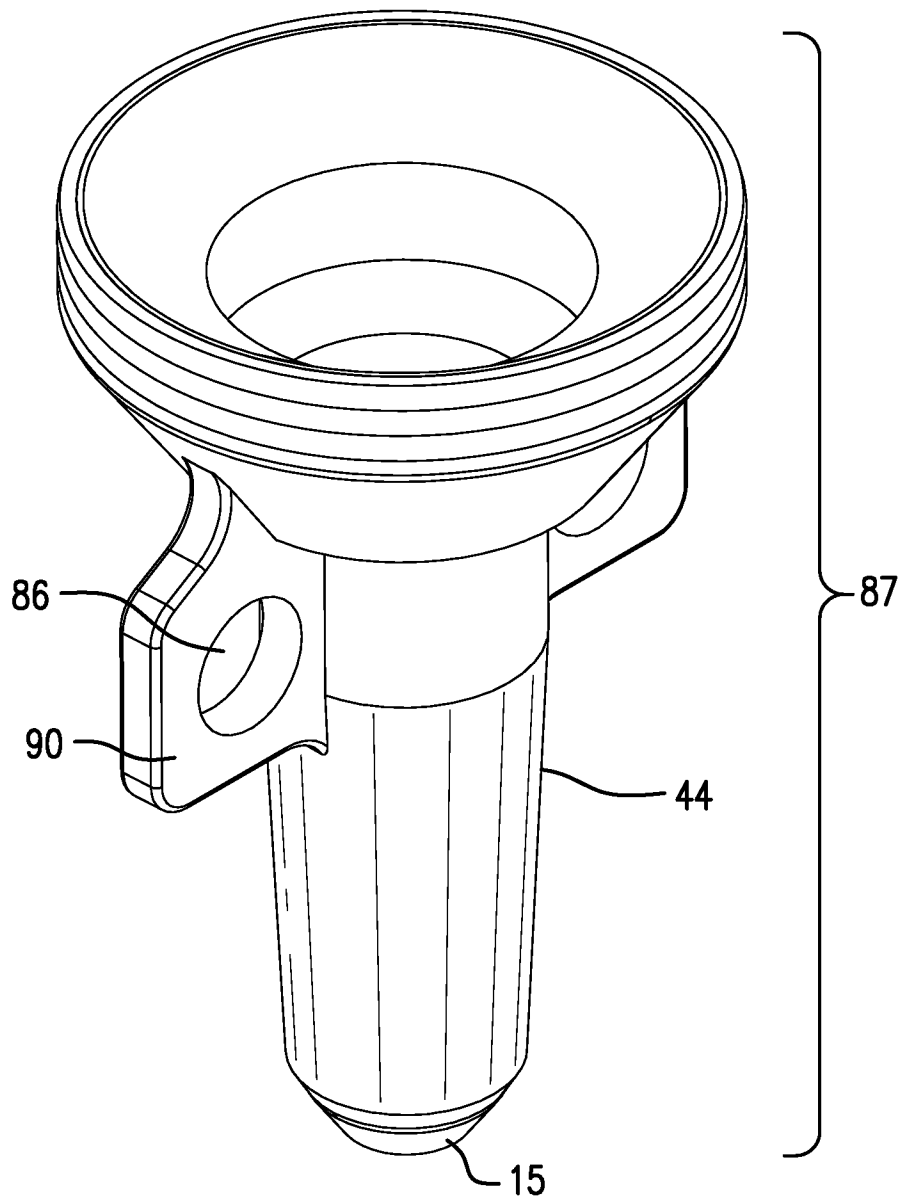


FIG. 7

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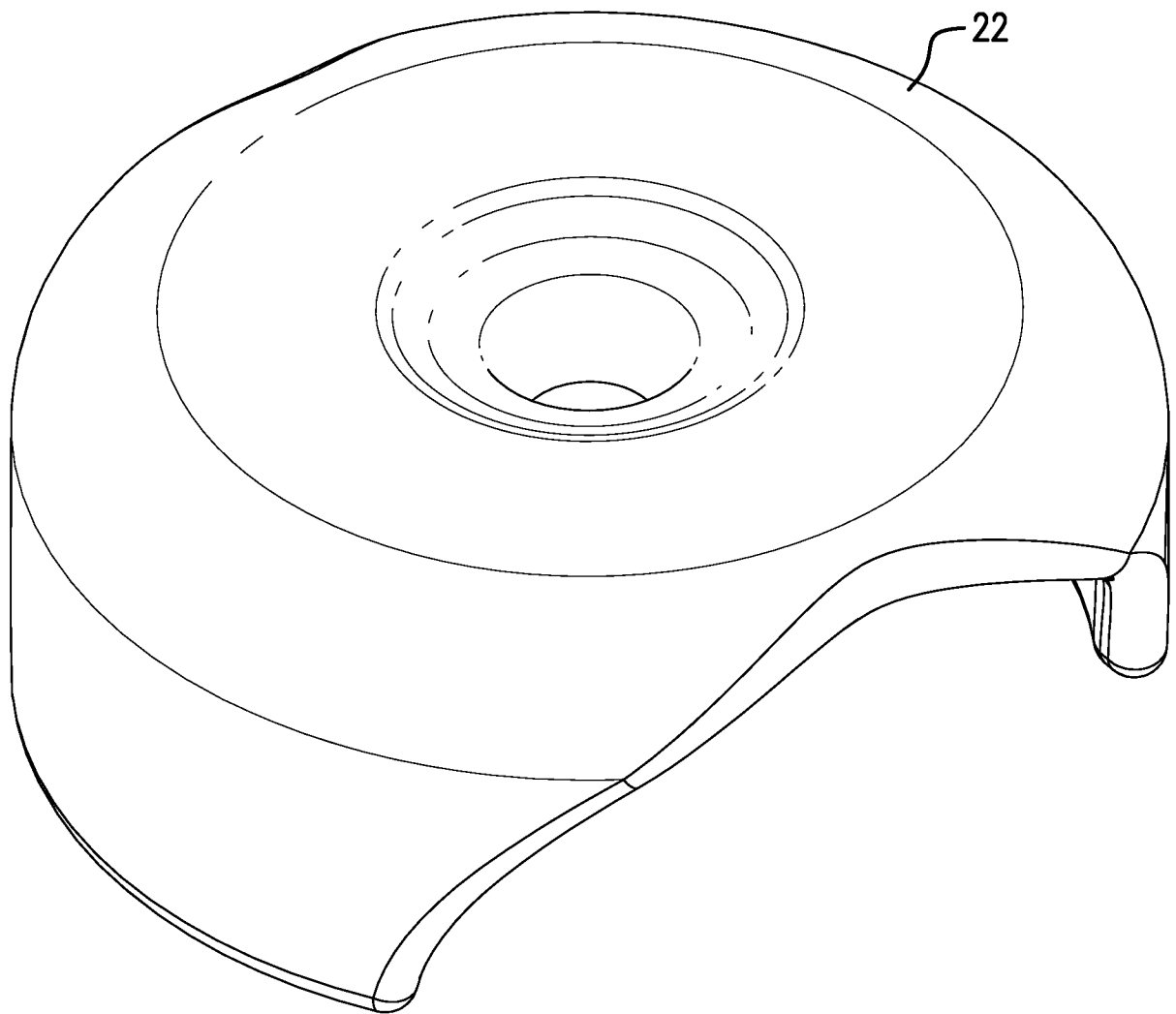


FIG. 8

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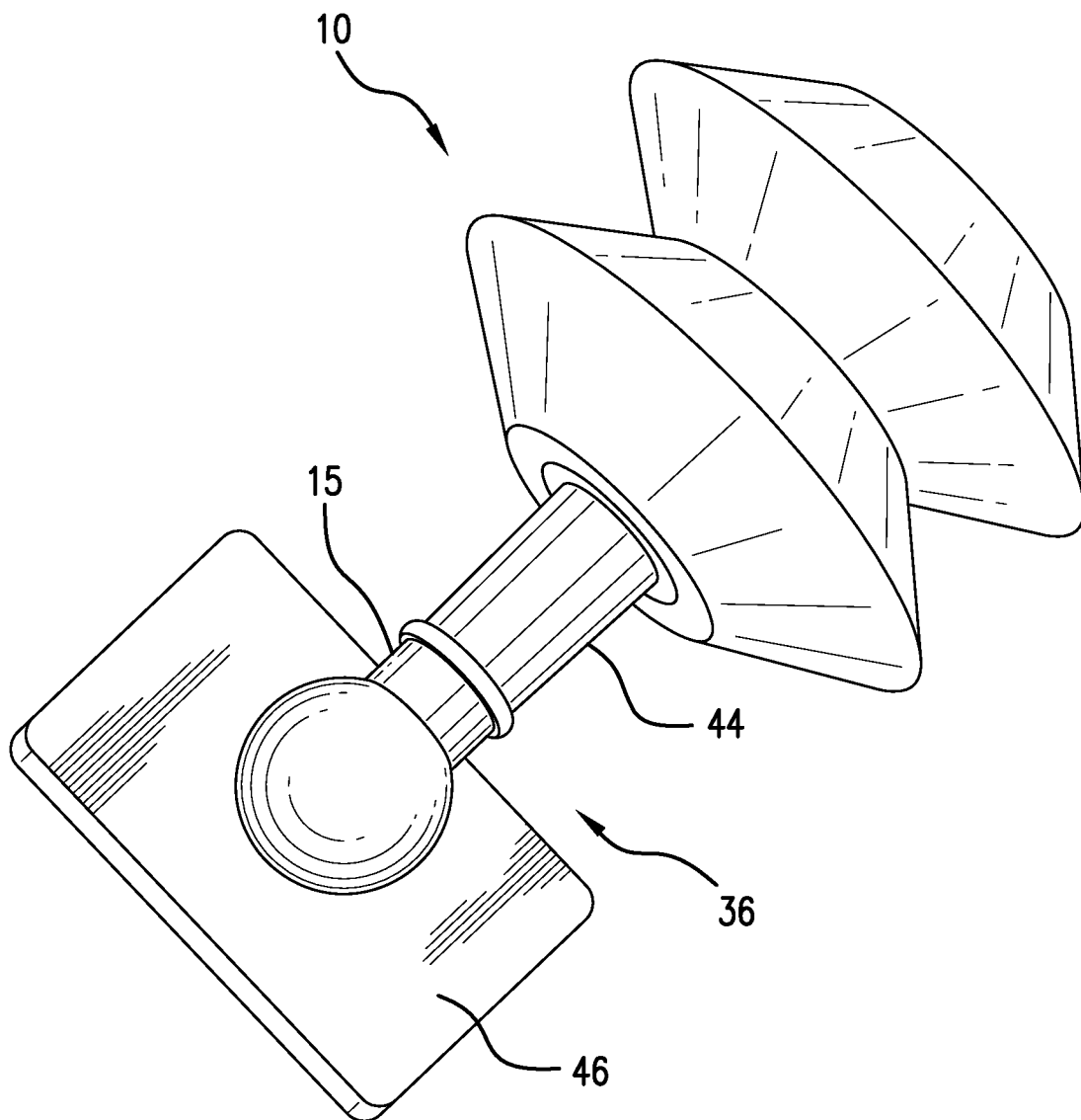


FIG. 9

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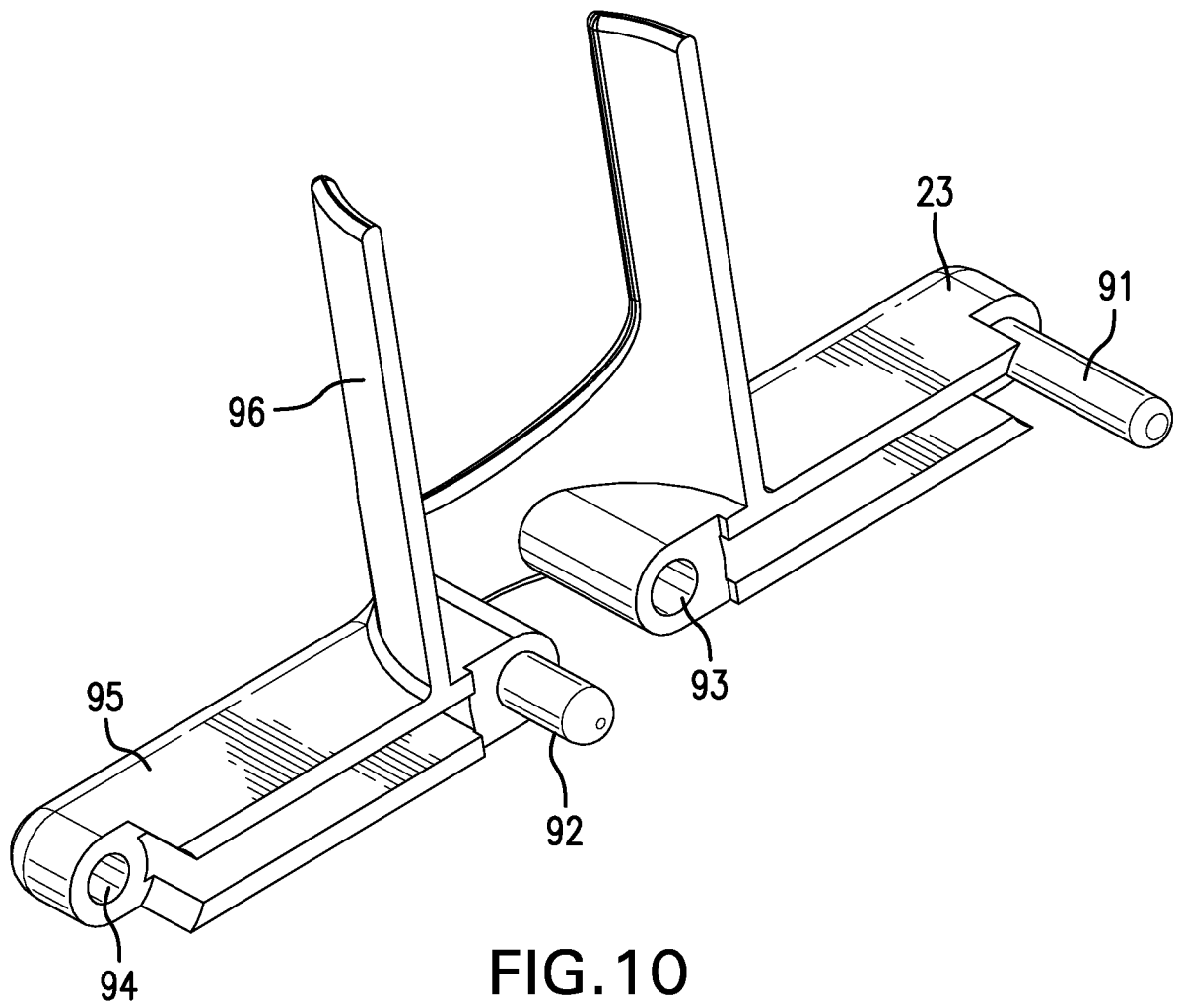


FIG. 10

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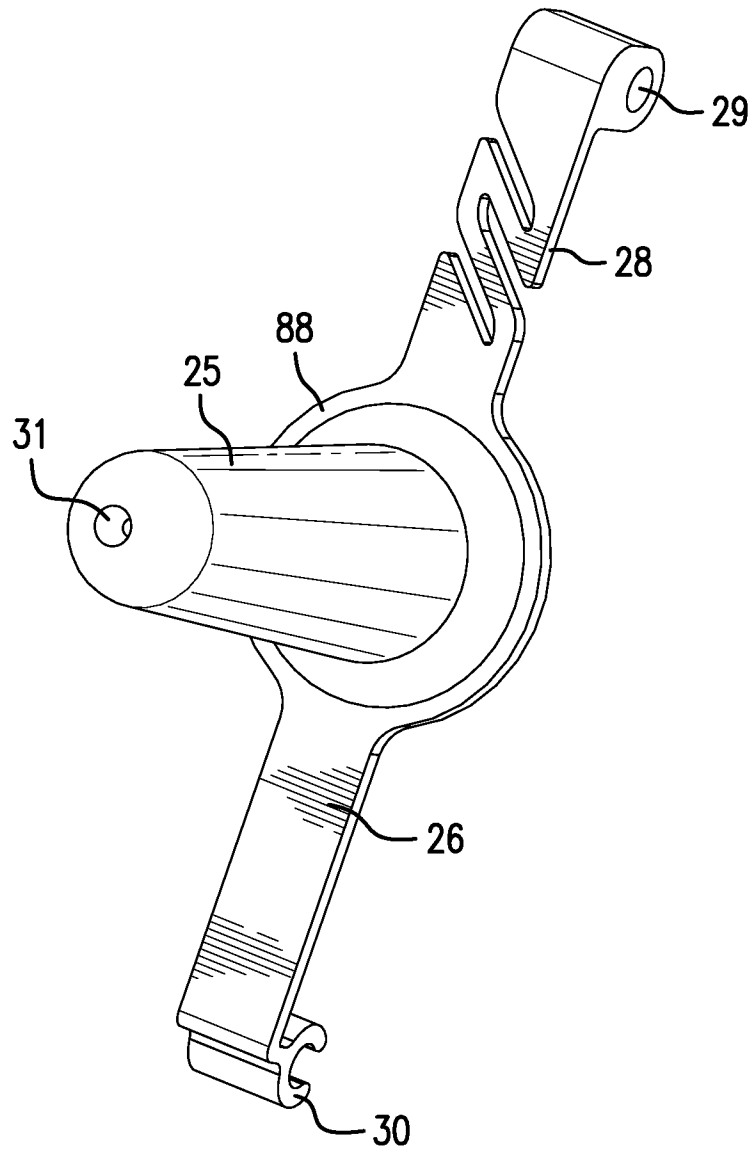


FIG. 11

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US16/62653

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61M15/00 (2017.01)

CPC - A61M15/00

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): A61M11/00; A61M13/00; A61M15/00; A61M5/00 (2017.01)

CPC: A61M15/0025 OR A61M15/0026 OR A61M15/0027 OR A61M5/00 OR A61M5/282

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)

PatSeer (US, EP, WO, JP, DE, GB, CN, FR, KR, ES, AU, IN, CA, INPADOC Data); Google Patents, Google/GoogleScholar, EBSCO, Ingenta Connect

KEYWORDS: dispens*, deliver*, discharge*, bellow*, contain*, collaps*, crush*, spring*, Bellevill*, drug*, medic*, powder*, liquid*, fluid*.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2013/0281940 A1, (MEDRAD, INC.), 24 October 2013 (24.10.2013), figures 7D-F; paragraph [0170]	1-14
Y	US 5,693,021 A, (DIAZ, J. et al.), 2 December 1997 (02.12.1997), figure 5; column 5, lines 44-57	1-14
Y	US 2012/0031398 A1, (BERGER et al.), 09 February 2012 (09.02.2012), figures 3, 8 and 9; paragraphs [0031] and [0039]	4
Y	WO 2015/074087 A1, (EXCELSIOR MEDICAL CORP.), 21 May 2015 (21.05.2015), figure 3b, page 8, lines 16-18	8-14
P, X	WO 2015/187518A1, (MERCK SHARP & DOHME CORP.), 10 December 2015 (10.12.2015), entire document	1-14
A	US 6,319,235 B1, (KOICHI, Y), 20 November 2001 (20.11.2001), entire document	1-14
A	US 3,938,514 A, (BOUCHER, LJ), 17 February 1976 (17.02.1976), entire document	1-14



Further documents are listed in the continuation of Box C.



See patent family annex.

*

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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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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

"&"

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Date of the actual completion of the international search

8 January 2017 (08.01.2017)

Date of mailing of the international search report

08 FEB 2017

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