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(71) Applicant: CRYOVAC, INC. [US/US]; 2415 Cascade Pointe Boulevard, Charlotte, North Carolina 28208 (US).

(72) Inventor: ROBERTS, William; 16016 Riverpointe Drive, Charlotte, North Carolina 28278 (US).

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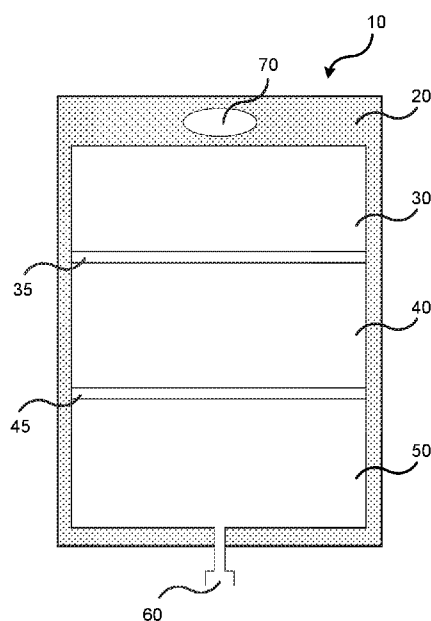


FIG. 1

(57) Abstract: A multi-chamber IV bag having two or more chambers for securely holding in a substantially unspoiled manner the same and/or different solutions. The chambers of the multi-layer IV bag are, at least in part, defined by frangible seals that are subjected to breaking allowing the solutions of each of the chambers to become mixed and administered to a patient. The manufacture of such a multi-chamber IV bag generally includes the steps of bringing two webs together along a vertically-oriented manufacturing line for the multi-chamber IV bag; inserting a port between the two webs at a first edge of the manufacturing line; sealing the two webs at the port; providing end seals at or near the first edge and diametrically opposed second edge of the two webs; forming one or more frangible seals between the end seals; introducing liquid between the two partially-sealed webs via two or more filling tubes that straddle the one or more frangible seals; and adding side seals and bag separation cuts at a second end of the manufacturing line. The use of such a multi-chamber IV bag includes the step of breaking at least one of frangible seals that at least in part define the chambers of the IV bag causing each solution to form a mixed solution followed by dispensing the mixed solution through a port.



MULTI-CHAMBER IV BAG AND METHOD OF PRODUCTION THEREOF

FIELD OF INVENTION

5 **[0001]** The present invention relates to a multi-chamber IV bag having two or more chambers for holding the same and/or different solutions. The present invention also provides the method of manufacturing such a multi-chamber IV bag.

BACKGROUND

10 **[0002]** Medical solutions are commonly administered intravenously through an IV bag, which is a sterile containment system. The administered solutions include any medical fluid, and may be a replacement body fluid or solutions that contain a drug or nutritional substance to be administered intravenously to the patient. IV bags typically are constructed such that the container is flexible and having a compartment for holding the administered solution. An outlet port is coupled to the compartment for administration and delivery of the solution to the patient.

15 Flexible containers manufactured under conventional processes typically require a multi-step manufacturing process to first form the container followed by filling the container with the solution to be administered followed by sealing off the route of filling.

20 **[0003]** In certain treatments, it is desired to administer a combination of compounds via the contained solution. Such an administration of solution may be considered a co-administration of a compound, composition, and/or pharmaceutical composition having one or more medicaments. Co-administration may involve, for example, the administration of two or more agents that may be found in the patient's bloodstream at the same time, regardless of when or how they are actually administered or a combination of such agents found in the patient's bloodstream with one or more medicaments.

25 [0004] The agents and/or medicaments may be administered simultaneously. Such combined
administration is accomplished by combining the agents in a single dosage form through a
physically mixing (e.g., by co-dissolution or dry mixing) or may form an adduct or be covalently
linked such that they split into the two or more active ingredients upon administration to the
patient. The agents may alternatively be administered sequentially conventionally through the
30 use of more than one IV bag.

[0005] Simultaneous administration of a combination of one or more agents and/or one or more
medicaments is sometimes limited by the ability of those agents and/or medicaments to be
combined in solution in an IV bag and stored for an extended period of time. Such agents and/or
medicaments may exhibit a negative effect on each other when stored together for a long period
35 of time. There remains a need in the art for an IV bag that allows a combination of agents and/or
medicaments to be administered to a patient in a simultaneous administration from a single IV
bag, but yet without such agents and/or medicaments losing their effectiveness when stored over
time.

SUMMARY OF INVENTION

40 [0006] The present invention relates to a multi-chamber IV bag. Without intending to be bound
by theory, a multi-chamber IV bag and techniques of the invention result in an IV bag suitable
for securely holding in a substantially unspoiled manner one or more solutions in distinct
chambers of the bag, whereby such solutions may eventually be delivered to a patient at a
desired time by breaking the frangible seals that at least in part define the chambers.

45 [0007] In one aspect, the invention provides a multi-chamber IV bag comprising two
diametrically opposed films having a perimeter seal to form a body of the multi-chamber IV bag;
a port surrounded by the perimeter seal at a bottom of the multi-chamber IV bag; at least one
frangible seal positioned inside the body and substantially parallel to the bottom; and two or
more chambers defined by the at least one frangible seal.

50 [0008] In an embodiment of the invention, the multi-chamber IV bag additionally comprises a hanging hole through the perimeter seal at a top of the multi-chamber IV bag. Further pursuant to this embodiment of the invention, the hanging hole may be positioned substantially at a center of the top.

55 [0009] In certain embodiments of the invention, a ratio of a volume of one of the two or more chambers to a volume of another of the two or more chambers is from about 1:1 to about 1:5. In certain other embodiments of the invention, the ratio of a volume of one of the two or more chambers to a volume of another of the two or more chambers is from about 1:1 to about 1:2.

60 [0010] In an embodiment of the invention, the two or more chambers of the multi-chamber IV bag may be filled with a solution and the solutions of each of the two or more chambers become combined upon a break in the at least one frangible seal. In certain embodiments of the invention, the break in the at least one frangible seal results from application of a pressure to the multi-chamber IV bag. According to certain embodiments of the invention, the solution of each of the two or more chambers are different.

65 [0011] Another aspect of the invention provides a method of manufacturing such a multi-chamber IV bag comprising the steps of bringing two webs together along a vertically-oriented manufacturing line for the multi-chamber IV bag; inserting a port between the two webs at a first edge of the manufacturing line; sealing the two webs at the port; providing end seals at or near the first edge and diametrically opposed second edge of the two webs; forming one or more frangible seals between the end seals; introducing liquid between the two partially-sealed webs
70 via two or more filling tubes that straddle the one or more frangible seals; and adding side seals and bag separation cuts at a second end of the manufacturing line.

[0012] In an embodiment of the invention, the method of manufacturing the multi-chamber IV bag may additionally comprise the following steps in another position of the two webs along the manufacturing line: cooling the end seals; and cutting a hanging hole through the end seal of the

75 second end. In certain embodiments of the invention, the method may additionally comprise filling each chamber that is defined by the one or more frangible seals with a solution in a finished multi-chamber IV bag. Further pursuant to this embodiment of the invention, the solution of each chamber are different

[0013] In an embodiment of the invention, the two webs used in forming the multi-chamber IV
80 bag are one of a double-wound web and two single-wound webs.

[0014] Yet another aspect of the invention provides a method of using a multi-chamber IV bag having the steps of providing a multi-chamber IV bag comprising two diametrically opposed films having a perimeter seal to form a body of the multi-chamber IV bag, a port surrounded by the perimeter seal at a bottom of the multi-chamber IV bag, at least one frangible seal positioned
85 inside the body and substantially parallel to the bottom, and two or more chambers defined by the at least one frangible seal each having a solution; breaking the at least one frangible seal causing each solution to form a mixed solution; and dispensing the mixed solution through the port.

[0015] According to an embodiment of the invention, the breaking of the at least one frangible
90 seal is through applying a pressure to the multi-chamber IV bag. According to certain embodiments of the invention, the solution of each of the two or more chambers are different.

[0016] Other aspects and embodiments will become apparent upon review of the following description taken in conjunction with the accompanying drawings. The invention, though, is pointed out with particularity by the included claims.

95 BRIEF DESCRIPTION OF THE DRAWINGS

[0017] The present invention relates to a multi-chamber IV bag. Having thus described the invention in general terms, reference will now be made to the accompanying drawings, which are not necessarily drawn to scale, and wherein:

100 [0018] FIG. 1 is a plan view of a multi-chamber IV bag according to an embodiment of the invention;

[0019] FIG. 2 is a plan view of a multi-chamber IV bag as currently known in the art;

[0020] FIG. 3 is a plan view showing the web alignment of the multi-chamber IV bags of the invention;

105 [0021] FIG. 4 is a plan view illustrating the filling and sealing of each of the chambers of the multi-chamber IV bag of the invention with separate filling tubes and sealing zones;

[0022] FIG. 5 is a plan view illustrating the port insertion and creation of the vertical and horizontal seals of the multi-chamber IV bag of the invention;

[0023] FIG. 6 is a schematic plan view of a first position of a machine that may be used to manufacture the multi-chamber IV bags of the invention; and

110 [0024] FIG. 7 is a schematic plan view of a second position of a machine that may be used to manufacture the multi-chamber IV bags of the invention.

DETAILED DESCRIPTION OF THE INVENTION

[0025] The present invention now will be described more fully hereinafter with reference to the accompanying drawings, in which some, but not all embodiments of the inventions are shown.

115 Preferred embodiments of the invention may be described, but this invention may, however, be embodied in many different forms and should not be construed as limited to the embodiments set forth herein. Rather, these embodiments are provided so that this disclosure will be thorough and complete, and will fully convey the scope of the invention to those skilled in the art. The embodiments of the invention are not to be interpreted in any way as limiting the invention.

120 **[0026]** As used in the specification and in the appended claims, the singular forms “a”, “an”, and “the” include plural referents unless the context clearly indicates otherwise. For example, reference to “a film” includes a plurality of such films.

[0027] It will be understood that relative terms, such as “preceding” or “followed by” or the like, may be used herein to describe one element’s relationship to another element as, for example, may be illustrated in the Figures. It will be understood that relative terms are intended to encompass different orientations of the elements in addition to the orientation of elements as illustrated in the Figures. It will be understood that such terms can be used to describe the relative positions of the element or elements of the invention and are not intended, unless the context clearly indicates otherwise, to be limiting.

130 **[0028]** Embodiments of the present invention are described herein with reference to various perspectives, including, for example, perspective views that are representations of idealized embodiments of the present invention. As a person having ordinary skill in the art would appreciate, variations from or modifications to the shapes as illustrated in the Figures or the described perspectives are to be expected in practicing the invention. Such variations and/or
135 modifications can be the result of manufacturing techniques, design considerations, and the like, and such variations are intended to be included herein within the scope of the present invention and as further set forth in the claims that follow. The articles of the present invention and their respective components described or illustrated in the Figures are not intended to reflect a precise description or shape of the component of an article and are not intended to limit the scope of the
140 present invention.

[0029] Although specific terms are employed herein, they are used in a generic and descriptive sense only and not for purposes of limitation. All terms, including technical and scientific terms, as used herein, have the same meaning as commonly understood by one of ordinary skill in the art to which this invention belongs unless a term has been otherwise defined. It will be further
145 understood that terms, such as those defined in commonly used dictionaries, should be interpreted as having a meaning as commonly understood by a person having ordinary skill in the art to which this invention belongs. It will be further understood that terms, such as those defined in commonly used dictionaries, should be interpreted as having a meaning that is consistent with their meaning in the context of the relevant art and the present disclosure. Such
150 commonly used terms will not be interpreted in an idealized or overly formal sense unless the disclosure herein expressly so defines otherwise.

[0030] The invention described herein relates to a multi-chamber IV bag. In certain embodiments of the invention, the multi-chamber IV bag comprises, as the name implies, a plurality of separate chambers. In preferred embodiments of the invention, the plurality of
155 separate chambers are fluid-containing chambers. In certain embodiments of the invention, the chambers comprise solutions that would otherwise not be favorable to combine in a single solution until just prior to their use. In certain embodiments of the invention, the chambers of the multi-chamber IV bag comprise solutions that will be distributed in a time-based manner. In an embodiment of the invention, the multi-chamber IV bag of the invention may be formed using a
160 vertical assembly process, as further described herein.

[0031] FIG. 1 is a plan view of a multi-chamber IV bag according to an embodiment of the invention. The multi-chamber IV bag **10** of FIG. 1 comprises two diametrically opposed films having a perimeter seal **20** surrounding a plurality of chambers, for example, a first chamber **30**, a second chamber **40** and a third chamber **50** as shown in this exemplary embodiment. Further
165 pursuant to the exemplary embodiment of FIG. 1, a first frangible seal **35** and a second frangible seal **45** separates the first chamber **30** and the second chamber **40** and the second chamber **40** and the third chamber **50**, respectively. The multi-chamber IV bag **10** also comprises a port **60**. The

drainage point 60 may also be considered a “spike” port. The exemplary embodiment of the multi-chamber IV bag 10 also comprises a hanging hole 70; however, the hanging hole 70 may be of various different geometric representations, number of hanging holes and position(s) of any such hole(s).

[0032] According to an embodiment of the invention, the port 60 is configured to drain solution from the multi-chamber IV bag 10. Additionally, the first frangible seal 35 and the second frangible seal 45 are capable of being broken by, for example, the application of pressure to one or more of the compartments of the multi-chamber IV bag 10. In addition to the application of pressure, other configurable means that are well-known in the art may be used to break the frangible seals to allow the solutions in each of the compartments to become combined.

[0033] In certain embodiments of the invention, the chambers of the multi-chamber IV bag may comprise different solutions, in particular, solutions where it is not preferred to mix certain components of the solutions together at the time the package is created and filled. Certain drug and/or nutrient formulations that are administered intravenously do not have the desired stability to survive the incumbent autoclave and/or storage conditions without degradation. For example, a pre-mixed solution of such components may interact in such a way that their combined effectiveness and/or performance is not the same once the mixed solution having the components is delivered from the bag. In some cases, for example, certain components may decrease their effectiveness upon combination for a long period of time. In certain other examples, certain components may physically or chemically interact over an extended storage time and/or variation in storage conditions to cause the formation, for example, of less desirable compounds. In yet certain other examples, a pH needed for stability of one compound in a solution varies from the pH needed for stability of another compound in solution. Parenteral nutrition and amino acid solutions are often kept separate sugar solutions, requiring separate administration. While which combinations are typically well-known requiring separate administration, without intending to be bound by the theory, the multi-chamber IV bags of the invention overcome these problems or any other problems that may arise from a premixing of the solutions comprising the components

195 by allowing the components to remain separated, but, yet, easily combined once the bag is ready for use.

[0034] As further shown in FIG. 1, the orientation of the frangible seals is horizontal when the bag is positioned with the drainage point down. Notably, only one of the chambers comprises a drainage port allowing for the combined solution to become dispensed from the bag. In other
200 embodiments of the invention, the multi-chamber IV bag may each enclose solutions that may be administered over time in multiple doses. According to this use, the multi-chamber IV bag allows for such administrations to be countably controlled. In yet other embodiments of the invention, varying solutions themselves may be administered according to a treatment methodology over time with the multi-chamber IV bag providing the capability to control and
205 monitor such varying treatments. Indeed, as a person having ordinary skill in the art may contemplate, having the benefit of this disclosure, the multi-chamber IV bag of the invention has many uses in the application of multiple doses of single compounds, dosing of multiple compounds, or any combination thereof.

[0035] A schematic view of a multi-chamber IV bag currently used in the art for such separate
210 distributions is shown in FIG. 2. The multi-chamber bag **110** known in the prior art itself comprises a perimeter seal **120** encompassing a plurality of chambers, for example, a first chamber **130**, a second chamber **140** and a third chamber **150**. A first vertical seal **135** and a second vertical seal **145** separates the first chamber **130** and the second chamber **140** and the second chamber **140** and the third chamber **150**, respectively. The multi-chamber IV bag **110** of
215 the prior art also comprises a first port **162**, a second port **164** and a third port **164** for filling and/or dispensing the solutions contained in the first chamber **130**, the second chamber **140** and the third chamber **150**, respectively. The multi-chamber IV bag **110** also comprises a hanging hole **170**.

[0036] In contrast to the multi-chamber IV bag of the invention with an exemplary embodiment
220 shown in FIG. 1, the multi-chamber IV bag of the prior art shown in FIG. 2 is normally

manufactured through the formation of the entire bag with all seals present and in an empty state. After the bag is manufactured, each chamber is filled with a different solution via the corresponding open port followed by the port being capped or sealed off. At least one of the resulting capped ports may later serve as a dispensing port after the seals between the chambers are ruptured. Thus, the multi-chamber bag of the prior art involves separate formation options—
225 e.g., sealing, filling and capping of multiple chambers). Accordingly, each chamber must have a port for filling. Thus, it is more costly to manufacture and subsequently fill the multi-chamber bag of the prior art. Additionally, the equipment needed to manufacture the bag of the prior art is more expensive, requires more labor as a result of the increased number of steps for
230 manufacturing and solution filling, increased floor space for operations, and a higher overall cost associated materials to manufacture the bag (additional ports).

[0037] An aspect of the invention provides the manufacture of the multi-chamber IV bag. FIG. 3 is a plan view that shows the web alignment of the multi-chamber IV bags of the invention. In particular, FIG. 3 shows two multi-chamber IV bags as illustrated in FIG. 1 together in a web
235 configuration **100**. The direction of formation of the web configuration **100** of the multi-chamber IV bags is horizontal as shown in FIG. 3.

[0038] FIG. 4 is a plan view illustrating the filling and sealing of each of the chambers of the multi-chamber IV bag of the invention with separate filling tubes, the completion of all perimeter seals, and the cutting apart of individual bags from a continuous web. As shown in FIG. 4, the
240 web configuration **200** is vertical, and each port **60'** is in a closed capped state to prevent the leakage of a solution as the multi-chamber IV bag is being filled. In the exemplary embodiment of FIG. 4, a first solution **92** contained in the first channel or chamber **30**, a second solution **94** contained in the second channel or chamber **40** and a third solution **96** contained in the third channel or chamber **50** are added using a first fill tube **97**, a second fill tube **98**, and a third fill
245 tube **99**, respectively. The solutions are represented by the variation in hashed lines of FIG. 4 and they may be same as, or different from, one another in contents and composition. Liquid level **90** represents the level of the solutions within the chambers..

[0039] Each of the multi-chamber IV bags may be separated by a portion of the web configuration **200** having a horizontal seal and cut region **80**. The lower bag **20** in FIG. 4 is a fully formed bag containing solutions, port and seals. The upper bag **20'** in FIG. 4 is not yet sealed on all sides and is being filled with solutions **92, 94, 96**.

[0040] The web configuration **200** of FIG. 4 is downwardly indexing as the multi-chamber IV bags are assembled, filled and then cut off at the bottom of the multi-chamber IV bag vertically preceding it. In a preferred embodiment of the invention, the web configuration **200** has an intermittent indexing motion whereby one bag length is moved for motion with the seals being made by immobile seal sections while the web configuration **200** is stationary. In another embodiment of the invention, a continuously moving web configuration **200** may comprise mobile or rotating seal tooling to seal the bag.

[0041] FIG. 5 is a plan view illustrating the port insertion and creation of the vertical and horizontal seals of the multi-chamber IV bag of the invention. FIG. 5 includes a web configuration **300** comprising a multi-chamber IV bag that has already been assembled and filled **310**, a multi-chamber IV bag that has already been assembled and is currently being filled **320**, a multi-chamber IV bag that is partially assembled **330** and a multi-chamber IV bag that is beginning to be assembled **340**. The multi-chamber IV bag that is partially assembled **330** in the exemplary embodiment of FIG. 5 has vertical perimeter seals **22, 24**; frangible seals **35, 45**; and a hanging hole **70**.

[0042] Referring to FIG. 5, after ply separation of the two film webs, the first fill tube **97**, second fill tube **98** and third fill tube **99** enter between the plies and extend through multi-chamber IV bag that is beginning to be assembled **340** and the multi-chamber IV bag that is partially assembled **330** to fill the multi-chamber bag that has already been assembled and is currently being filled **320**.

[0043] Either a double-wound web or two single-wound webs may be brought together at the multi-chamber IV bag that is beginning to be assembled 340. Near the top of the multi-chamber IV bag that is beginning to be assembled 340, the two plies are separated to allow the plies to surround the first fill tube 97, the second fill tube 98 and the third fill tube 99. FIG. 5 illustrates how the port 60' is inserted and the creation vertical perimeter seals 22, 24 is completed below the entry point of the first fill tube 97, the second fill tube 98 and the third fill tube 99, but before the liquid level 90 is reached. Vertical frangible seals, such as the first frangible seal 35 and a the second frangible seal 45 illustrated in FIG. 5, divide the combined web into two or more isolated channels to keep the solutions, such as the first solution 92, the second solution 94 and the third solution 96 in the three chamber IV bag illustrated in FIG. 5, separate while completing the formation of the multi-chamber IV bag containing such solutions.

[0044] FIGs. 4 and 5 are simplified schematic views showing the generalized essential steps for multi-chamber IV bag formation and the filling of the bag with solutions. As would be understood by a person of ordinary skill in the art having the benefit of this disclosure, the manufacture of the multi-chamber IV bag and the filling of the multi-chamber IV bag may require additional process steps that have not been illustratively shown. For example, voiding nip roles may be used to intermittently open and close just above the horizontal seal and cut region 80 to help prevent wrinkling in the horizontal seal and cut region 80.

[0045] In a preferred embodiment of the invention, the seals of the multi-chamber IV bag are heat seals, but any alternative means to provide a seal to the multi-chamber IV bag known in the art may be used. For example, without intending to be limiting, either radio frequency (RF) welding, also known as high frequency (HF) or dielectric welding, and/or ultrasonic welding may be used in addition to or instead of a heat seal. Laminated high-barrier films may also be used for the packaging of highly oxygen-sensitive solutions.

[0046] In an embodiment of the invention, the frangible seals may be produced by any one of or any combination of the use of a lower heat seal temperature, a lower seal time, and a lower seal pressure relative to the conditions used to provide the permanent seals.

300 [0047] In an embodiment of the invention, the port 60 and the port 60' is any spike port conventionally used in the manufacture of IV bags. In a preferred embodiment of the invention, the port 60 and the port 60' is an injection-molded hard plastic spike port.

305 [0048] The multi-chamber IV bag may be at least one of printed or overwrapped as otherwise known in the art. For example, such methods may include, but are not limited to, hot stamp, thermal transfer, ink jet printing, on-line in certain embodiments, and flexo/gravure typically through the use of a separate printing press. In a preferred embodiment of the invention, the film of the multi-chamber IV bag is printed in line with the manufacture of and the sealing operations associated with the bag as shown, for example, in FIGs. 4 and 5.

310 [0049] A finished multi-chamber IV bag may be subjected to sterilization after its manufacture, either before or after an overwrapping step has been completed. In certain embodiments of the invention, the multi-chamber IV bag may be manufactured from a pre-sterilized film, solution and port components in an aseptic process.

315 [0050] The volume of the multi-compartment IV bag may be adjusted to accommodate the treatment method the multi-chamber IV bag is intended to be used for. In an embodiment of the invention, the multi-chamber IV bag has a total volume ranging from about 0.1 to about 5 liters, from about 0.2 to about 4 liters, from about 0.5 to about 3 liters, or, in a preferred embodiment of the invention, from about 1 to about 2 liters. According to an embodiment of the invention, a volume for each compartment of the multi-chamber IV bag is at least about 50 ml, at least about 100 ml, at least about 250 ml, or at least about 1,000 ml.

[0051] In an embodiment of the invention, the location of the frangible seals and overall multi-chamber IV bag dimensions may be varied to contain different compartment volumes relative to each other. In certain embodiments of the invention, the ratio of volume of the smallest compartment to the volume of the largest compartment is from about 1:10, from about 1:5, from about 1:4, from about 1:3, from about 1:2, from about 2:3, from about from about 4:5, or from about 8:9. In certain embodiments of the invention, the volumes of the compartments of the multi-chamber IV bag are substantially the same. Indeed, the volumes of the various compartments may be configured to best support the intended treatment us of such a bag.

[0052] FIG. 6 is a schematic plan view of a first position of a machine that may be used to manufacture the multi-chamber IV bags of the invention. A first step in the manufacture of the multi-chamber IV bag of the invention comprises bringing two webs together, which can be either a double-wound web or two single-wound webs. The manufacturing system **400** shown in FIG. 6 further includes a step for inserting and sealing a port **410** at an end of the multi-chamber IV bag, providing an end seal **420**, cooling the end seal **430** and forming a port gap seal **440** in the end at the terminus of the end seal. A step of forming one or more frangible seals **450** is also included. Development of the end seal opposite the end seal surrounding the port includes the steps of first forming the opposite end seal **460** followed by cooling the opposite end seal **470**. Once the multi-chamber IV bag has been taken through these steps of the manufacturing process, the steps of forming and cutting the side seals **490** are performed. The steps **420**, **430**, **450**, **460** which are in association with the end seal, the one or more frangible seals and the opposite end seal of section **475** are performed in both positions of a downwardly indexing web having the indexing repeat length as indicated in FIG. 6, while other steps are performed only in the position shown in this FIG. 6 (i.e., port seal **410**, gap seal **440**, and horizontal seals and cut **490**) or the position illustrated in FIG. 7 as further discussed herein.

[0053] FIG. 7 is a schematic plan view of a second position of a machine that may be used to manufacture the multi-chamber IV bags of the invention. As with the first position illustrated in FIG. 6, this position includes steps of providing an end seal **420**, cooling the end seal **430**,

forming one or more frangible seals **450**, forming the opposite end seal **460** and cooling the opposite end seal **470**. Position 2 also includes the unique step of cutting a hanging hole **480** at the opposite end seal.

350 [0054] Many modifications and other embodiments of the invention set forth herein will come to mind to one skilled in the art to which this invention pertains having the benefit of the teachings presented in the descriptions herein and the associated drawings. It will be appreciated by those skilled in the art that changes could be made to the embodiments described herein without departing from the broad inventive concept thereof. Therefore, it is understood that this invention is not limited to the particular embodiments disclosed, but it is intended to cover modifications
355 within the spirit and scope of the present invention as defined by the included claims.

CLAIMS

That which is claimed:

1. A multi-chamber IV bag comprising:
two diametrically opposed films having a perimeter seal to form a body of the multi-
360 chamber IV bag;
a port surrounded by the perimeter seal at a bottom of the multi-chamber IV bag;
at least one frangible seal positioned inside the body and substantially parallel to the
bottom; and
two or more chambers defined by the at least one frangible seal.
- 365 2. The multi-chamber IV bag of claim 1, additionally comprising a hanging hole through the
perimeter seal at a top of the multi-chamber IV bag.
3. The multi-chamber IV bag of claim 2, wherein the hanging hole is positioned
substantially at a center of the top.
4. The multi-chamber IV bag of claim 1, where a ratio of a volume of one of the two or
370 more chambers to a volume of another of the two or more chambers is from about 1:1 to about
1:5.
5. The multi-chamber IV bag of claim 1, where a ratio of a volume of one of the two or
more chambers to a volume of another of the two or more chambers is from about 1:1 to about
1:2.
- 375 6. The multi-chamber IV bag of claim 1, wherein the two or more chambers are filled with a
solution and each of the solution of the two or more chambers become combined upon a break in
the at least one frangible seal.
7. The multi-chamber IV bag of claim 6, wherein the break in the at least one frangible seal
results from application of a pressure to the multi-chamber IV bag.

- 380 8. The multi-chamber IV bag of claim 6, wherein the solution of each of the two or more chambers are different.
9. A method of manufacturing a multi-chamber IV bag comprising:
bringing two webs together along a manufacturing line for the multi-chamber IV bag;
inserting a port between the two webs at a first edge of the manufacturing line;
385 sealing the two webs at the port;
providing end seals at the first edge and diametrically opposed second edge of the manufacturing line;
cooling the end seals;
forming one or more frangible seals between the end seals to produce partially-sealed
390 webs;
introducing a liquid between the two partially-sealed webs with two or more filling tubes that straddle the one or more frangible seals; and
adding side seals and bag separation cuts at a second end of the manufacturing line.
10. The method of claim 9, additionally comprising the following steps in another position of
395 the two webs along the manufacturing line:
cooling the end seals; and
cutting a hanging hole through the end seal of the second end.
11. The method of claim 10, additionally comprising filling each chamber that is defined by the one or more frangible seals with a solution in a finished multi-chamber IV bag.
- 400 12. The method of claim 11, wherein the solution of each chamber are different
13. The method of claim 9, wherein the two webs are one of a double-wound web and two single-wound webs.
14. A method of using a multi-chamber IV bag comprising:
providing a multi-chamber IV bag comprising two diametrically opposed films having a
405 perimeter seal to form a body of the multi-chamber IV bag, a port surrounded by the perimeter seal at a bottom of the multi-chamber IV bag, at least one frangible seal positioned inside the

body and substantially parallel to the bottom, and two or more chambers defined by the at least one frangible seal each having a solution;

breaking the at least one frangible seal causing each solution to form a mixed solution;

410 and

dispensing the mixed solution through the port.

15. The method of claim 14, wherein breaking the at least one frangible seal is by applying a pressure to the multi-chamber IV bag.

16. The method of claim 14, wherein the solution of each of the two or more chambers are
415 different.

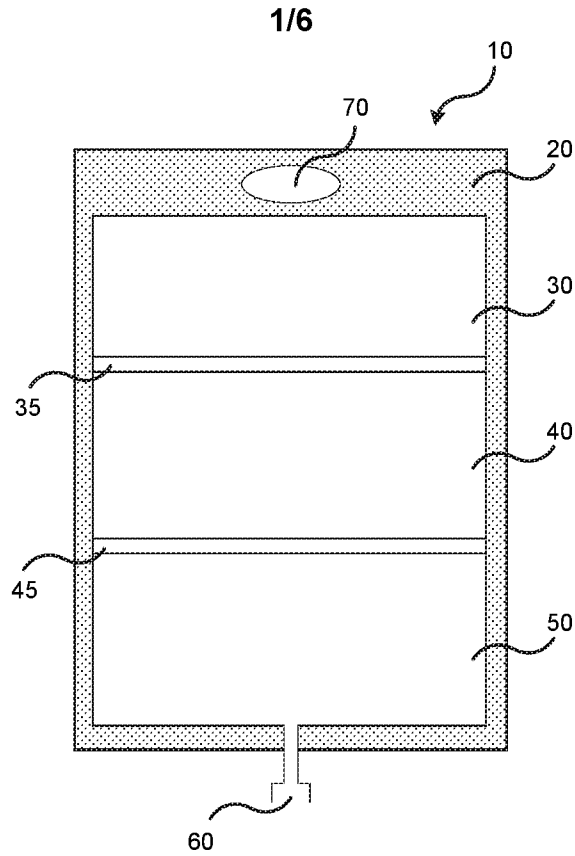


FIG. 1

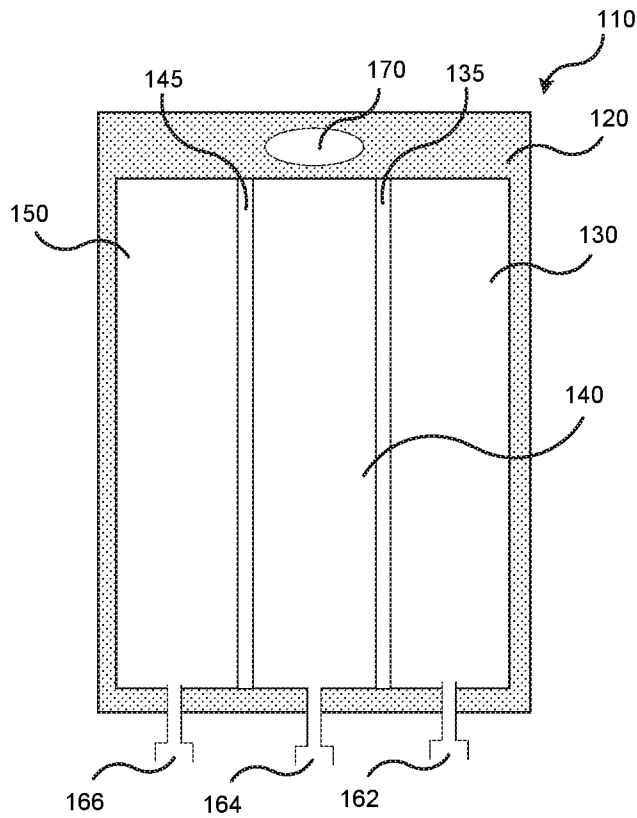


FIG. 2
(Prior Art)

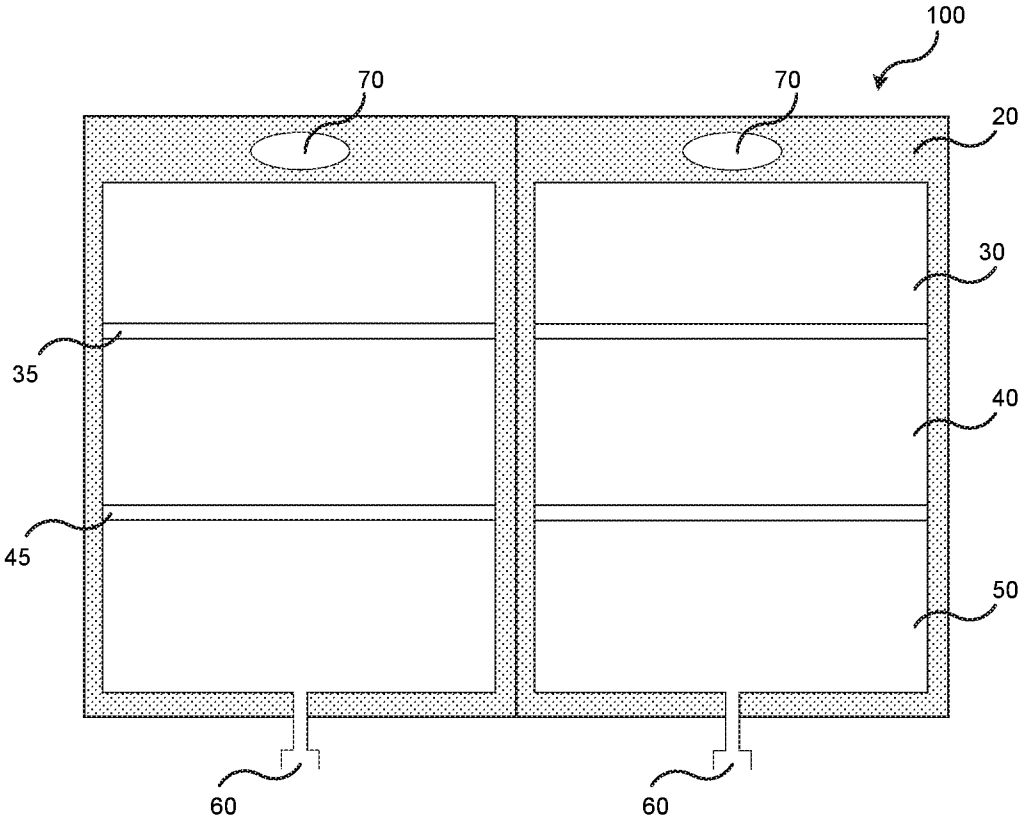


FIG. 3

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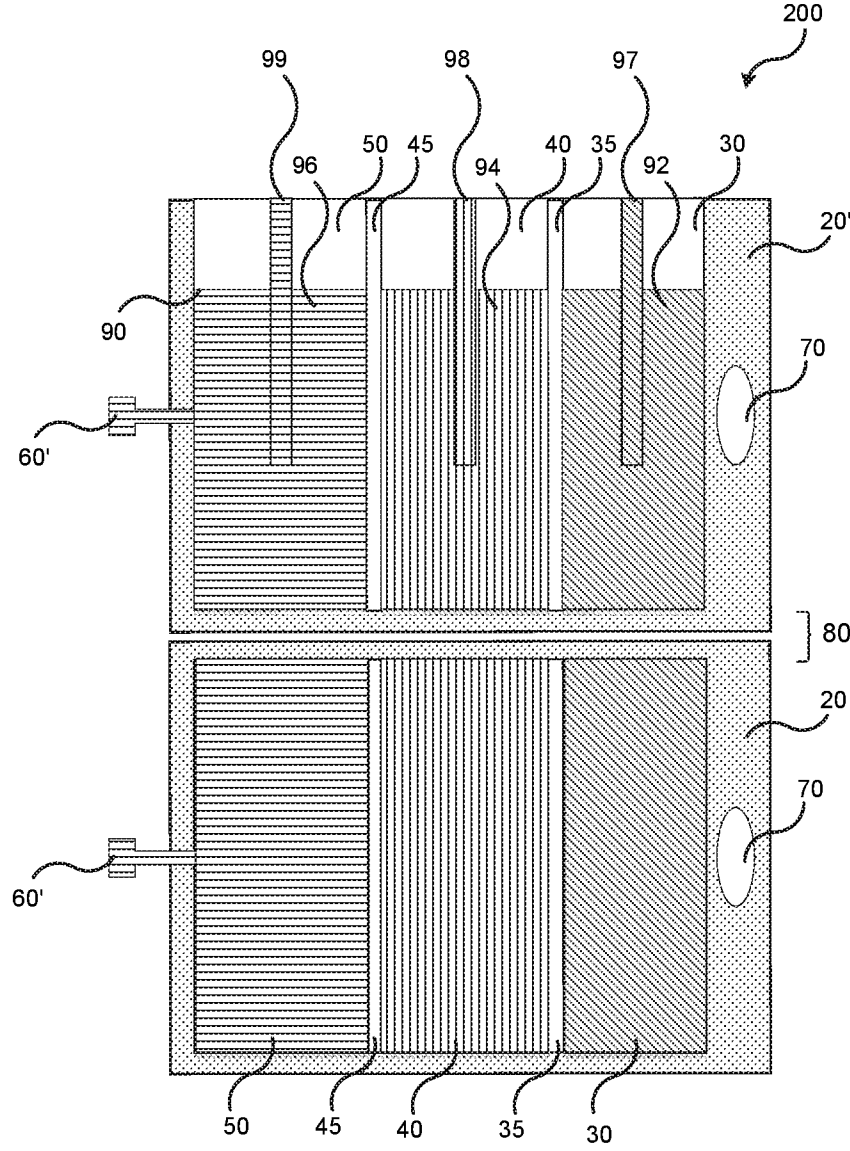


FIG. 4

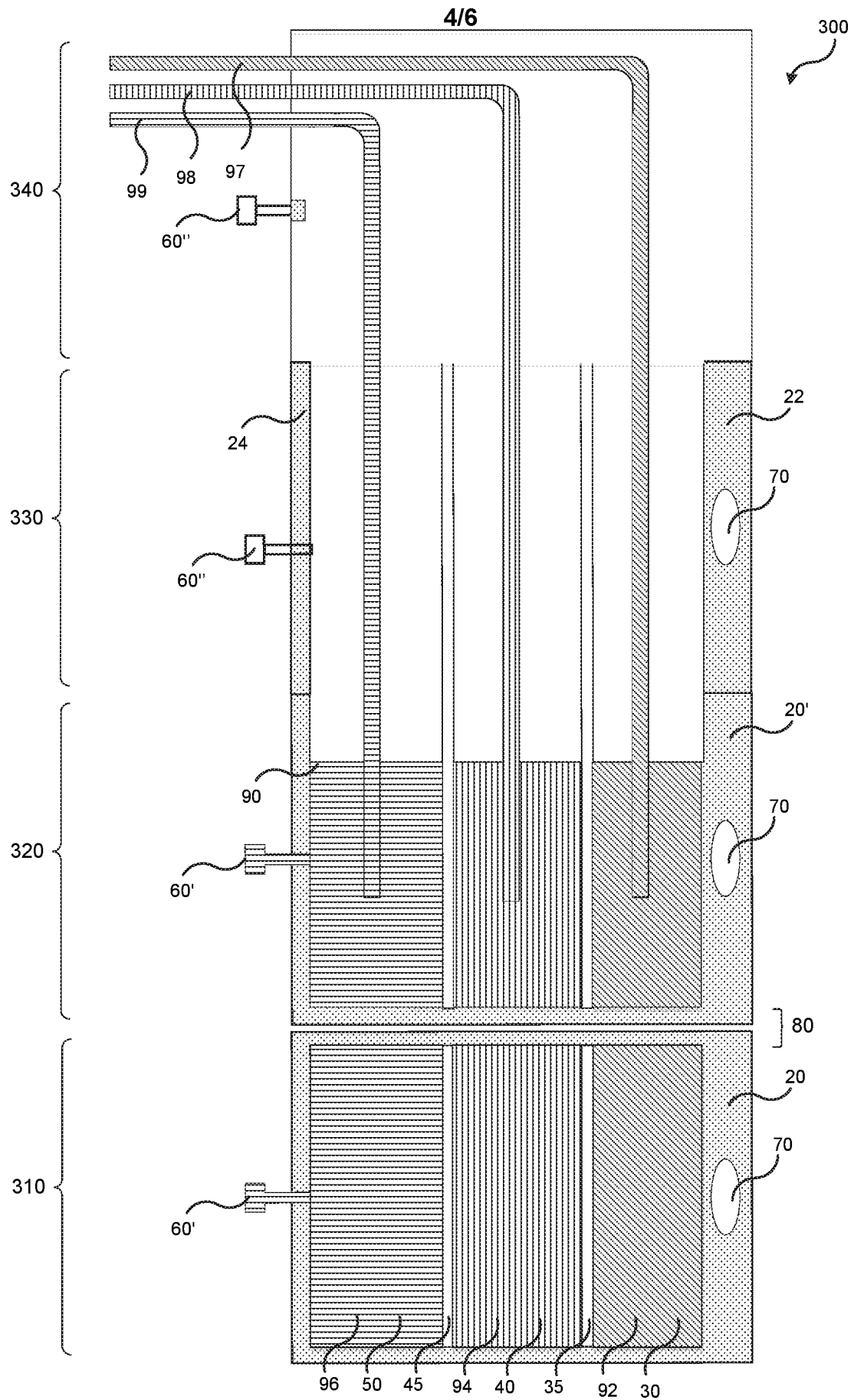


FIG. 5

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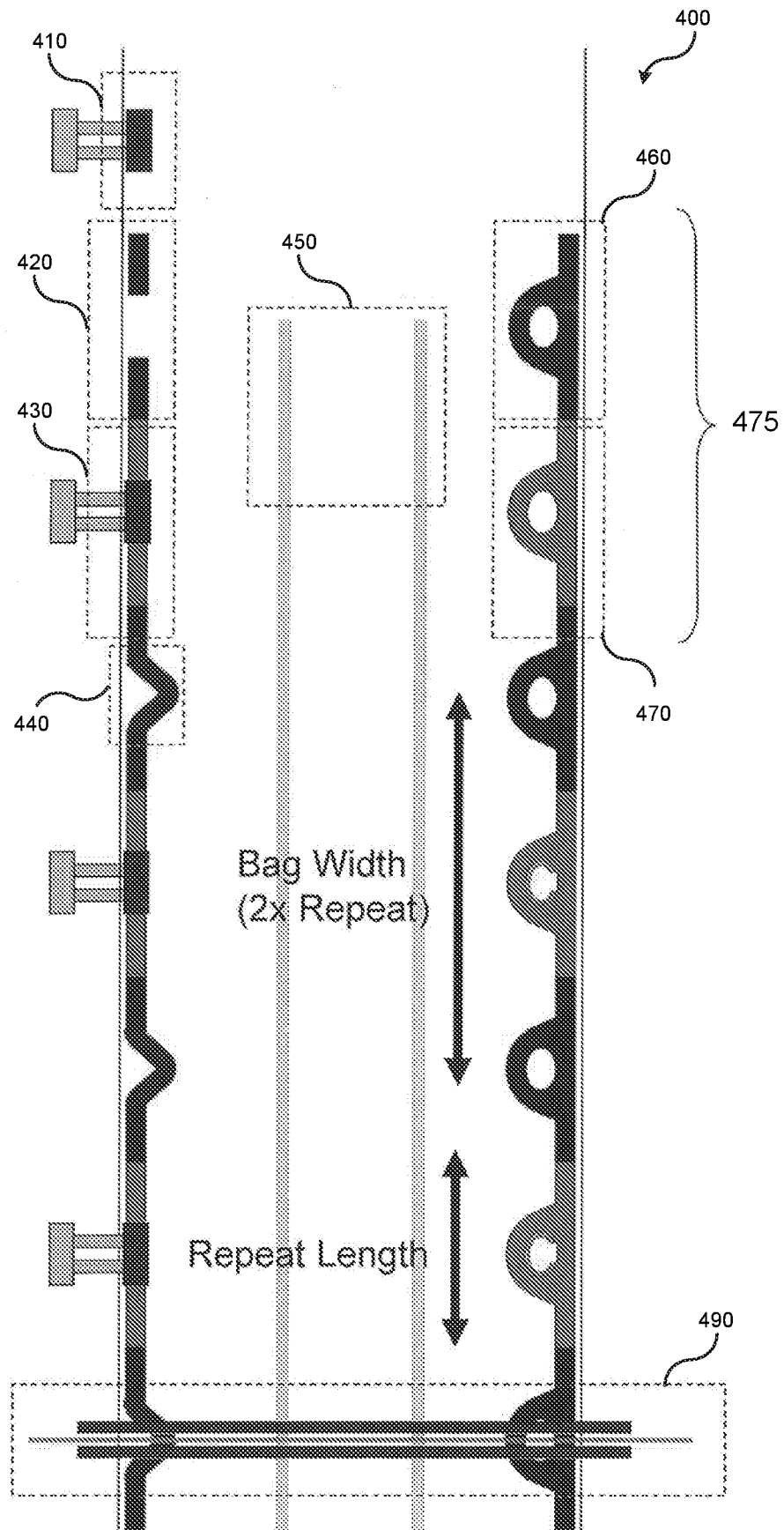


FIG. 6

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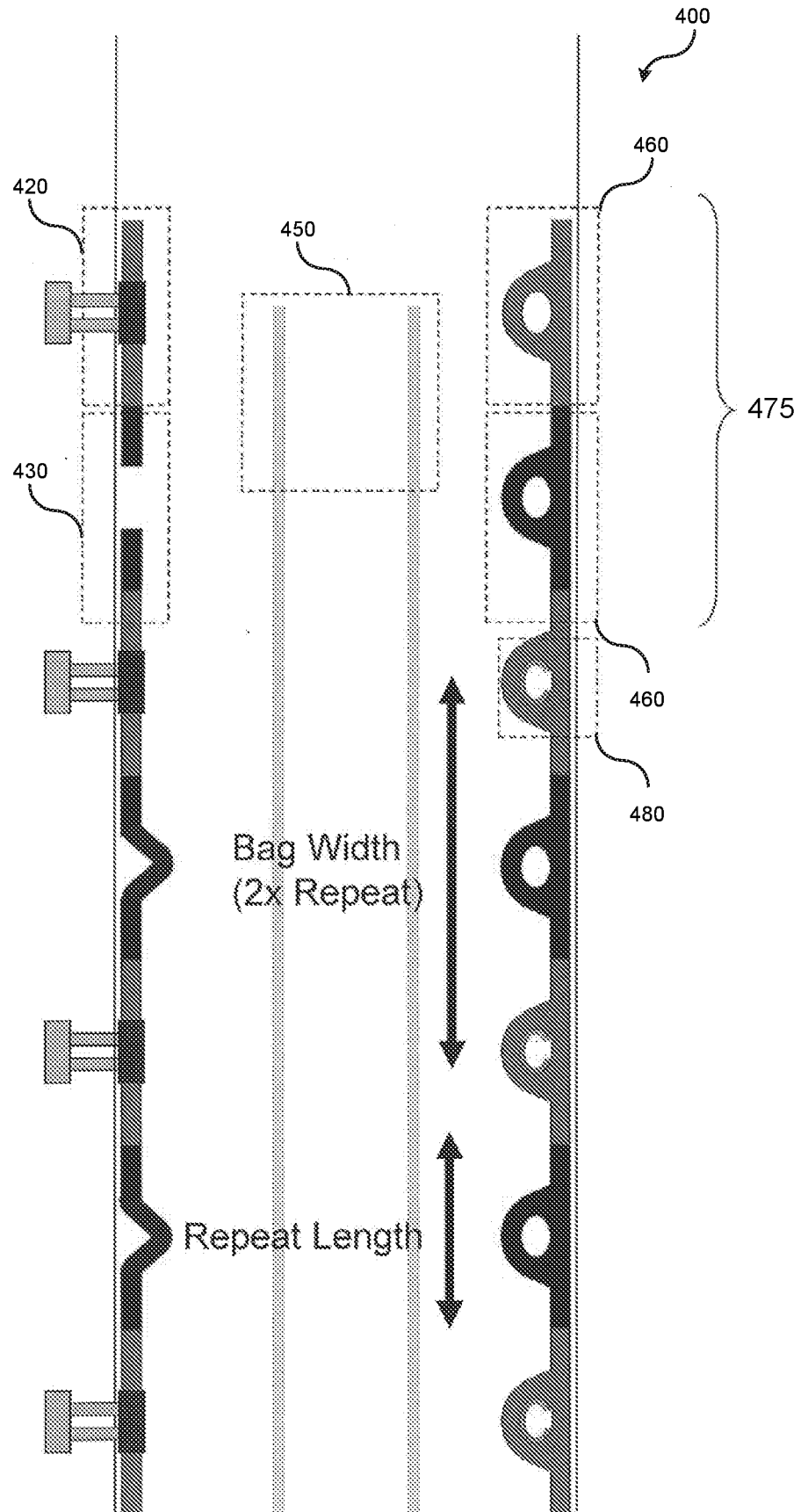


FIG. 7

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2017/053893

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61J1/10 A61J1/20
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)
A61J

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)

EPO-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.
X	US 6 306 473 B1 (DENPOU TAKAYUKI [JP] ET AL) 23 October 2001 (2001-10-23) column 3, line 39 - column 7, line 18 figures 1-3	1-8, 14-16
X	----- EP 1 779 831 A1 (AJINOMOTO KK [JP]) 2 May 2007 (2007-05-02) paragraph [0013] - paragraph [0048] figures 1, 2, 8, 9	1,14
X	----- EP 2 143 413 A1 (AJINOMOTO KK [JP]) 13 January 2010 (2010-01-13) paragraph [0014] - paragraph [0036] figures 1-9	1,14
	----- -/-	



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)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

5 December 2017

Date of mailing of the international search report

07/02/2018

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

Schiffmann, Rudolf

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2017/053893

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-8, 14-16

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2017/053893

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 2 108 355 A1 (AJINOMOTO KK [JP]) 14 October 2009 (2009-10-14) column 6 - column 13 figures 1-10 -----	1,14
X	WO 2010/082649 A1 (AJINOMOTO KK [JP]; SHIMIZU KAORU [JP]; MURAMATSU YASUHIRO [JP]) 22 July 2010 (2010-07-22) figures 1-11 abstract the whole document -----	1,14

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2017/053893

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FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-8, 14-16

film bag for IV solution mixing and dispensing and method of using including chambers defined by frangible seal to be broken

2. claims: 9-13

method of manufacturing a film bag for IV solution mixing and dispensing including adding bag separating cuts at the end of the manufacturing line
