United States Patent Application Publication	20250262125
Kind Code	A1
Publication Date	August 21, 2025
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METHOD OF MANUFACTURING BEFORE-USE DISSOLUTION INFUSION BAG

Abstract

Provided is a method of manufacturing a before-use dissolution infusion bag in which a pressing strength required for dissolution before use can be maintained to be low. A method of manufacturing a before-use dissolution infusion bag, includes: a sterilization step of sterilizing an infusion bag including two chambers for accommodating drugs and a weak sealed portion for isolating the two chambers from each other such that the two chambers are communicable with each other; a pinhole forming step of providing two pinholes in a strong sealed portion for isolating the chambers of the infusion bag and an outside from each other after the sterilization step; a positioning step of positioning the infusion bag and a cover sheet having pinholes such that the same pins are inserted into the pinholes formed in the infusion bag and the pinholes of the cover sheet, respectively, and the cover sheet covers an outer surface of one chamber among the two chambers; and a welding step of pressing a pressing member to weld the infusion bag and the cover sheet in a state where the infusion bag and the cover sheet are positioned, in which a straight line formed by connecting centers of the two pinholes formed in the infusion bag is positioned on the weak sealed portion.

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Appl. No.: **19/199617**

Filed: **May 06, 2025**

Foreign Application Priority Data

JP	2022-207987	Dec. 26, 2022

Related U.S. Application Data

parent WO continuation PCT/JP2023/042108 20231124 PENDING child US 19199617

Publication Classification

Int. Cl.: **A61J1/10** (20060101); **A61J1/20** (20060101)

U.S. Cl.:

CPC **A61J1/10** (20130101); **A61J1/2024** (20150501); **A61J1/2093** (20130101);

Background/Summary

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is a Continuation of PCT International Application No. PCT/JP2023/042108 filed on Nov. 24, 2023, which claims priority under 35 U.S.C. § 119(a) to Japanese Patent Application No. 2022-207987 filed on Dec. 26, 2022. The above applications are hereby expressly incorporated by reference, in their entirety, into the present application.

BACKGROUND OF THE INVENTION

1. Field of the Invention

[0002] The present invention relates to a method of manufacturing a before-use dissolution infusion bag.

2. Description of the Related Art

[0003] A before-use dissolution infusion bag that is used in a medical setting or the like, includes a plurality of chambers, and is partitioned by a communicable partition member is known. In the before-use dissolution infusion bag, for example, a drug having hygroscopicity (for example, an antibiotic) and a liquid drug such as a dissolving solution are accommodated in different chambers, and by pressing one chamber before use, the drug and the liquid drug are mixed through the partition member that partitions these chambers.

[0004] Typically, the before-use dissolution infusion bag is formed of a resin film having low gas barrier properties. In a case where the drug having hygroscopicity (for example, an antibiotic) is accommodated in the chamber of the before-use dissolution infusion bag, the drug or the like may absorb moisture such that the quality is changed. Therefore, a cover sheet having gas barrier properties is bonded to an outer surface of the chamber for accommodating the drug or the like of the before-use dissolution infusion bag to use the drug.

[0005] For example, JP1992-364851A (JP-H04-364851A) describes a multi-chamber container having flexibility where a plurality of chambers for accommodating a liquid drug, a powdered drug, or a solid medicine are partitioned by a communicable partition unit, the multi-chamber container including: a water-impermeable and/or gas-impermeable outer wall that covers the entirety of one chamber among the plurality of chambers; and a water-permeable and/or gas-permeable inner wall that configures a chamber covered with the outer wall, in which a space portion between the inner wall and the outer wall is encapsulated with a desiccant and/or an oxygen scavenger, and the chamber in the inner wall is encapsulated with a liquid drug, a powdered drug, or a solid medicine having easy oxidability and/or hygroscopicity.

SUMMARY OF THE INVENTION

[0006] This multi-chamber container (before-use dissolution infusion bag) is formed by sterilizing

a resin bag consisting of a resin film, encapsulating the resin bag with a drug, and welding and bonding a film having barrier properties to the resin bag.
[0007] As described above, in a case where the before-use dissolution infusion bag is used, by pressing one chamber, a chamber for accommodating a drug or the like having hygroscopicity and a chamber for accommodating a liquid drug such as a dissolving solution communicate with each other such that the drug and the liquid drug are mixed with each other (are dissolved before use). Therefore, the partition member that partitions the two chambers is bonded with a lower bonding strength than a bonding strength of peripheral ends of the resin bag.
[0008] Here, according to an investigation by the present inventors, it was found that, in order to reduce a pressing strength required for communication of the partition member that partitions the chamber for accommodating the drug or the like and the chamber for accommodating the liquid drug, the cover sheet needs to be bonded to the partition member (weak scaled portion) with high positional accuracy. In order to bond the cover sheet to the partition member with high accuracy, it is considered to provide a pinhole for positioning in each of the resin bag and the cover sheet such that, by allowing a pin to pass through the pinholes, the resin bag (partition member) and the cover sheet are positioned with high accuracy.
[0009] However, the resin bag includes a strong sealed portion that bonds the peripheral ends with a high bonding strength and a weak sealed portion (partition member) that is bonded with a weaker bonding strength than the strong sealed portion. Therefore, a form deformed by thermal contraction and/or thermal expansion due to heat or the like during sterilization cannot be expected. Therefore, it was found that, in a case where the pinhole for positioning is formed before sterilization, the shape and/or size of the pinhole is deformed and the accuracy cannot be ensured.
[0010] In addition, the entire resin bag is bent due to heat during sterilization. In addition, unpredictable deformation such as curling may be present in the cover sheet, and thus it is difficult to accurately fix the cover sheet on a plane.
[0011] Therefore, it was found that, simply even with the configuration of providing a pinhole for positioning in each of the resin bag and the cover sheet such that, by allowing a pin to pass through the pinholes, the resin bag (partition member) and the cover sheet are positioned with high accuracy, it is difficult to position the cover sheet relative to the partition member (weak sealed portion) with high positional accuracy.
[0012] As a result, it was found that there is a problem in that a pressing strength required for communication (dissolution before use) of the partition member (weak sealed portion) that partitions the chamber for accommodating the drug or the like and the chamber for accommodating the liquid drug increases.
[0013] An object of the present invention is to solve the above-described problem of the related art and to provide a method of manufacturing a before-use dissolution infusion bag in which a pressing strength required for dissolution before use can be maintained to be low.
[0014] In order to achieve the object, the present invention has the following configurations. [0015] [1] A method of manufacturing a before-use dissolution infusion bag, the method comprising:
[0016] a sterilization step of sterilizing an infusion bag including two chambers for accommodating drugs and a weak sealed portion for isolating the two chambers from each other such that the two chambers are communicable with each other; [0017] a pinhole forming step of providing two pinholes in a strong sealed portion for isolating the chambers of the infusion bag and an outside from each other after the sterilization step; [0018] a positioning step of positioning the infusion bag and a cover sheet having pinholes such that the same pins are inserted into the pinholes formed in the infusion bag and the pinholes of the cover sheet, respectively, and the cover sheet covers an outer surface of one chamber among the two chambers; and [0019] a welding step of pressing a pressing member to weld the infusion bag and the cover sheet in a state where the infusion bag and the cover sheet are positioned, [0020] in which a straight line formed by connecting centers of the two pinholes formed in the infusion bag is positioned on the weak sealed portion. [0021] [2] The

method of manufacturing a before-use dissolution infusion bag according to [1], [0022] in which in the welding step, an entire area of a welded portion surrounding the one chamber is simultaneously welded. [0023] [3] The method of manufacturing a before-use dissolution infusion bag according to [1], [0024] in which in the welding step, the infusion bag and the cover sheet are sequentially welded from a side of the two pinholes. [0025] [4] The method of manufacturing a before-use dissolution infusion bag according to [3], [0026] in which in the welding step, the infusion bag and the cover sheet are sequentially welded from the side of the two pinholes using the pressing member having a curved surface. [0027] [5] The method of manufacturing a before-use dissolution infusion bag according to [3], [0028] in which in the welding step, the infusion bag and the cover sheet are sequentially welded from the side of the two pinholes using the pressing member that is divided for each of blocks.

[0029] According to the present invention, it is possible to provide a method of manufacturing a before-use dissolution infusion bag in which a pressing strength required for dissolution before use can be maintained to be low.

Description

BRIEF DESCRIPTION OF THE DRAWINGS

[0030] FIG. **1** is a cross sectional view conceptually showing an example of a before-use dissolution infusion bag prepared using a method of manufacturing a before-use dissolution infusion bag according to the present invention.

[0031] FIG. **2** is a plan view showing the before-use dissolution infusion bag shown in FIG. **1**.

[0032] FIG. **3** is a conceptual diagram showing an example of the method of manufacturing a before-use dissolution infusion bag according to the present invention.

[0033] FIG. **4** is a conceptual diagram showing the example of the method of manufacturing a before-use dissolution infusion bag according to the present invention.

[0034] FIG. **5** is a conceptual diagram showing the example of the method of manufacturing a before-use dissolution infusion bag according to the present invention.

[0035] FIG. **6** is a conceptual diagram showing the example of the method of manufacturing a before-use dissolution infusion bag according to the present invention.

[0036] FIG. **7** is a conceptual diagram showing the example of the method of manufacturing a before-use dissolution infusion bag according to the present invention.

[0037] FIG. **8** is a conceptual diagram showing the example of the method of manufacturing a before-use dissolution infusion bag according to the present invention.

[0038] FIG. **9** is a conceptual diagram showing another example of the method of manufacturing a before-use dissolution infusion bag according to the present invention.

[0039] FIG. **10** is a conceptual diagram showing another example of the method of manufacturing a before-use dissolution infusion bag according to the present invention.

[0040] FIG. **11** is a diagram showing an action of dissolution before use in the before-use dissolution infusion bag.

[0041] FIG. **12** is a diagram showing a relationship of a positional relationship between a weak sealed portion and a cover sheet with a required pressing strength.

[0042] FIG. **13** is a diagram showing a relationship of a positional relationship between a weak sealed portion and a cover sheet with a required pressing strength.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0043] Hereinafter, a method of manufacturing a before-use dissolution infusion bag according to an embodiment of the present invention will be described in detail based on preferred examples shown in the accompanying drawings.

[0044] In the present invention, numerical ranges represented by “to” include numerical values

before and after “to” as lower limit values and upper limit values.

Before-Use Dissolution Infusion Bag

[0045] First, a configuration of a before-use dissolution infusion bag prepared using the method of manufacturing a before-use dissolution infusion bag according to the embodiment of the present invention will be described.

[0046] FIG. **1** conceptually shows an example of the before-use dissolution infusion bag prepared using the method of manufacturing a before-use dissolution infusion bag according to the embodiment of the present invention. FIG. **2** is a top view showing the before-use dissolution infusion bag of FIG. **1**. FIG. **1** is a cross sectional view taken along a line A-A in FIG. **2**.

[0047] A before-use dissolution infusion bag **100** shown in FIGS. **1** and **2** includes a resin bag (bag body) **102** and two cover sheets **10**.

[0048] In the before-use dissolution infusion bag **100**, the resin bag **102** and the cover sheet **10** are bonded to each other by thermal welding (heat sealing) through a sealant layer. In addition, in the example shown in the drawing, peripheral portions of the resin bag **102** and the cover sheets **10** are bonded to form a space therebetween.

Resin Bag

[0049] As shown in FIGS. **1** and **2**, the resin bag **102** is a bag where peripheral ends of two resin films are joined through a strong sealed portion **104** or a bag where one resin film is folded and peripheral ends are joined through the strong sealed portion **104**. The strong sealed portion **104** through which the peripheral ends of the resin films are joined is a sealed portion for isolating a chamber of the resin bag **102** and the outside from each other.

[0050] In addition, as shown in FIGS. **1** and **2**, the resin bag (bag body) **102** includes two chambers **108** and **110**, and the two chambers are partitioned by a weak sealed portion (partition member) **106**. In addition, the weak sealed portion **106** is a sealed portion having a weaker bonding strength than the strong sealed portion **104** where the peripheral ends of the resin films are joined. In the example shown in FIG. **2**, all of the peripheral ends of the two resin films substantially having a rectangular shape are joined through the strong sealed portion **104** to form an inner space. In FIG. **2**, the inner space is separated into the two chambers **108** and **110** by the weak sealed portion **106** extending from the strong sealed portion **104** on an upper end side to the strong sealed portion **104** on a lower end side.

[0051] Examples of a material of the resin bag **102** (resin film) include a resin film such as a polyethylene resin or a polypropylene resin. In addition, in the case of the bag where two resin films are joined, the two resin films may be films consisting of different materials and are preferably films consisting of the same material. In a case where the films consisting of the same material are bonded to each other using a heat sealing method, the films can be easily bonded to each other.

[0052] The thickness of the resin film of the resin bag **102** is preferably 20 to 200 μm.

[0053] The strong sealed portion **104** and the weak sealed portion **106** can be formed using a heat sealing method.

[0054] In addition, a method of forming the weak sealed portion **106** is not particularly limited as long as the weak sealed portion **106** has a weaker bonding strength than the strong sealed portion **104**. By changing conditions (a temperature, a pressing strength, and the like) during heat sealing during the formation of the strong sealed portion **104**, the weak sealed portion **106** having a weaker bonding strength may be formed. By heat-sealing the two resin films with different kinds of resin layers interposed therebetween at a position where the weak sealed portion **106** is formed, the weak sealed portion **106** may have a weaker bonding strength than the strong sealed portion **104**. By scattering the strong sealed portions having a small area that can be fractured in an airtightly closed region, the weak sealed portion **106** having a sea-island structure that exhibits the same weak sealing function in a macro manner may be formed.

[0055] The bonding strengths of the strong sealed portion **104** and the weak sealed portion **106** may

be adjusted to be in well-known ranges in the related art. As described in JIS Z 0238:1998, the bonding strength of the strong sealed portion **104** is preferably 23 N/15 mm or more, and the bonding strength of the weak sealed portion **106** is preferably 3 N/15 mm or less.

[0056] In the resin bag **102**, typically, peripheral ends (end parts) of the resin film other than a necessary outlet (for example, a liquid discharge port of an infusion bag) may be completely joined.

[0057] The kind of the resin bag (bag body) **102** is preferably used for packaging a product that requires gas barrier properties. Examples of the product to be packaged include food, non-food, and chemical. The state of the product to be packaged may be liquid, solid, or powdered. It is preferable that, by appropriately performing heat sealing, the packaging material is bag-shaped. Specific examples of the packaging material include a packaging bag for food, a packaging bag for chemical, and an infusion bag.

Infusion Bag

[0058] In a case where the resin bag **102** is an infusion bag, for example, one chamber **108** accommodates a liquid drug such as a dissolving solution, and the other chamber **110** accommodates a drug having hygroscopicity (for example, an antibiotic). In this case, the cover sheet **10** is bonded to an outer side surface of the chamber **110** for accommodating a drug having hygroscopicity.

[0059] In the infusion bag, the weak sealed portion **106** is peeled off immediately before use, the liquid drug and the drug are mixed, and the mixture is infused from the liquid discharge port.

[0060] Examples of the drug used in the infusion bag include liquid to be administered under the skin or into the blood vessel or abdominal cavity by drip infusion or the like. In the case of the duplex bag, examples of the drug include powdered drug and liquid such as saline. Examples of the powder drug include a nutrient such as vitamin or amino acid, an antibiotic, and an antibacterial agent.

[0061] In addition, within a range not departing from the scope of the present invention, techniques described in JP2003-230618A and JP1998-201818A (JP-H10-201818A) can be considered.

Cover Sheet

[0062] The cover sheet **10** is a film-shaped member having gas barrier properties. The cover sheet **10** is bonded to at least one of the outer side surfaces of the chamber **110** for accommodating the drug or the like having hygroscopicity in the resin bag **102**, that is, the surfaces of the resin film opposite to the chamber **110**. In addition, as shown in FIG. **1**, it is preferable that a peripheral end of the cover sheet **10** is bonded to the resin film. As a result, the drug or the like having hygroscopicity can be prevented from absorbing moisture, and the quality can be prevented from being changed.

[0063] As the cover sheet **10**, a well-known cover sheet that can be used for a before-use dissolution infusion bag in the related art can be appropriately used.

[0064] Examples of the cover sheet **10** include a metal foil such as aluminum foil, a laminated film where a metal layer such as aluminum is formed on a resin film, and a gas barrier film such as silicon nitride or silicon oxide where an inorganic layer and an organic layer are laminated described in JP2015-171798A, JP2014-024602A, and the like.

[0065] In addition, in a case where the two cover sheets **10** are bonded to both of the outer side surfaces of the chamber **110** of the resin bag **102**, respectively, the two cover sheets **10** may be the same kind of films or may be different kinds of films. From the viewpoint that the inside of the chamber **110** is visible, one cover sheet **10** is preferably a gas barrier film where an inorganic layer and an organic layer are laminated.

[0066] The sealant layer (thermal welding layer) is bonded to the cover sheet **10**, and the cover sheet **10** is bonded to the resin bag **102** by heat sealing (thermal welding (thermal fusion)).

Sealant Layer

[0067] The sealant layer is a layer for bonding the cover sheet **10** to an object by heat sealing

(thermal welding (thermal fusion)).
[0068] Basically, the sealant layer is formed of the same forming material as the object to which the cover sheet is heat-sealed. For example, in a case where the object is an infusion bag, the sealant layer is formed of the same material as the material for forming the infusion bag. That is, in a case where the object to be heat-sealed is formed of polyethylene (PE), a sheet-shaped material (film-shaped material) formed of PE may be used as the sealant layer, and in a case where the object to be heat-sealed is formed of polypropylene (PP), a sheet-shaped material (film-shaped material) formed of PP may be used as the sealant layer.
[0069] Specifically, as the material for forming the sealant layer, a resin film described in paragraph [0015] of JP2012-075716A can be used.
[0070] In addition, the thickness of the sealant layer is not also limited, and may be appropriately selected depending on the material for forming the sealant layer and the shape, state, or the like of the object such as an infusion bag to be heat-sealed such that the object can be reliably thermally welded. Here, according to the study by the present inventors, the thickness of the sealant layer is preferably 5 to 150 μm, more preferably 10 to 100 μm, and still more preferably 30 to 70 μm. The thickness of the sealant layer is preferably 5 μm or more from the viewpoints that, for example, more reliable heat sealing can be performed and unevenness of a surface of the object to be heat-sealed can be suitably absorbed. The thickness of the sealant layer is preferably 150 μm or less from the viewpoints that, for example, the thickness of the before-use dissolution infusion bag can be reduced and permeation of water vapor and/or oxygen from a side surface of the sealant layer during thermal welding of the infusion bag or the like can be more effectively suppressed.
Adhesive Layer
[0071] An adhesive layer is a layer for bonding the sealant layer and the cover sheet **10**.
[0072] As the adhesive layer, all of well-known adhesives through which the sealant layer can adhere to the cover sheet **10** can be used.
[0073] In addition, the thickness of the adhesive layer is not limited, and may be appropriately selected such that the sealant layer can reliably adhere to the cover sheet **10**.
Method of Manufacturing Before-Use Dissolution Infusion Bag
[0074] A method of manufacturing a before-use dissolution infusion bag according to the embodiment of the present invention, comprises: [0075] a sterilization step of sterilizing an infusion bag including two chambers for accommodating drugs and a weak sealed portion for isolating the two chambers from each other such that the two chambers are communicable with each other; [0076] a pinhole forming step of providing two pinholes in a strong sealed portion for isolating the chambers of the infusion bag and an outside from each other after the sterilization step; [0077] a positioning step of positioning the infusion bag and a cover sheet having pinholes such that the same pins are inserted into the pinholes formed in the infusion bag and the pinholes of the cover sheet, respectively, and the cover sheet covers an outer surface of one chamber among the two chambers; and [0078] a welding step of pressing a pressing member to weld the infusion bag and the cover sheet in a state where the infusion bag and the cover sheet are positioned, [0079] in which a straight line formed by connecting centers of the two pinholes formed in the infusion bag is positioned on the weak sealed portion.
[0080] The method of manufacturing a before-use dissolution infusion bag according to the embodiment of the present invention (hereinafter, also referred to as the manufacturing method according to the embodiment of the present invention) will be sequentially described.
[0081] The manufacturing method according to the embodiment of the present invention includes the welding step of bonding (thermally welding) the cover sheet **10** after the sterilization step of sterilizing the above-described resin bag (bag body, infusion bag) **102**, forms the pinholes in the resin bag **102** (pinhole forming step) before the welding step and after the sterilization step, positions the cover sheet **10** using the pinholes (positioning step), and positions the straight line formed by connecting the centers of the pinholes on the weak sealed portion.

Sterilization Step

[0082] The sterilization step is a step of performing a well-known sterilization method in the related art, for example, sterilization by high-pressure steam, sterilization by hydrogen peroxide gas, electron beam sterilization, or gamma sterilization in the manufacturing of the before-use dissolution infusion bag.

[0083] In general, in the manufacturing of the before-use dissolution infusion bag, after disposing the two resin films to form the weak sealed portion **106**, the strong sealed portion **104** other than a region where a portion for charging the drug is formed is formed. Next, after providing a port on the chamber **108** side for accommodating the drug or further filling the chamber **108** with the chemical liquid and closing the port, the sterilization step is performed.

Pinhole Forming Step

[0084] The pinhole forming step is a step of providing two pinholes in the strong sealed portion for isolating the chambers of the resin bag **102** and the outside from each other after the sterilization step.

[0085] The pinhole forming step is performed between the sterilization step and the welding step.

[0086] In general, after the sterilization step, the drug is put into the chamber **110** that is opened, the opening is sealed and closed (strongly sealed), and the resin bag **102** and the cover sheet are welded (welding step). Accordingly, after the sterilization step, the pinhole forming step may be performed before putting the drug into the chamber **110** and closing and sealing the opening. Alternatively, the pinhole forming step may be performed after putting the drug into the chamber **110** and closing and sealing the opening.

[0087] Here, in the pinhole forming step, as shown in FIG. **3**, the pinholes are formed such that a straight line formed by connecting the centers of the two pinholes **30** is positioned on the weak sealed portion **106**. That is, the pin hole is formed in the vicinity of each of both ends of the weak sealed portion **106** in a longitudinal direction. In this case, the position of the pinhole **30** may be set with reference to a marker printed on the resin bag **102**, may be set with reference to the strong sealed portion **104** or the weak sealed portion **106**, or may be set with reference to an end side of the resin bag **102**. It is preferable that the positions of the two pinholes **30** are preferably set with reference to the end side of the weak sealed portion **106** on the chamber **108** side. For example, it is preferable that the positions are set such that a straight line formed by connecting the centers of the two pinholes **30** is substantially parallel to the end side of the weak sealed portion **106** on the chamber **108** side at a predetermined distance. The straight line formed by connecting the centers of the two pinholes **30** may be non-parallel to the end side of the weak sealed portion **106** on the chamber **108** side.

[0088] In FIGS. **3** and **5**, the shape of an invisible portion of the object is also indicated by a solid line.

[0089] A method of forming the pinholes **30** in the pinhole forming step is not particularly limited, and a well-known processing method such as punching or laser processing may be used.

[0090] In addition, the size and shape of the pinholes **30** are not limited as long as the pin can be inserted into the pinholes **30**, and are preferably the same as a cross sectional shape of the pin. The shape of the pinholes **30** is preferably circular. In addition, the circle-equivalent diameter of the pinholes **30** may be appropriately set depending on the stiffness of the resin film, and is preferably 5 mm to 15 mm.

[0091] In addition, the distance between the two pinholes **30** may be appropriately set depending on the shape of the resin bag **102** and the like.

Positioning Step

[0092] The positioning step is performed after the pinhole forming step and is a step of positioning the resin bag **102** and the cover sheet **10** having two pinholes **130** shown in FIG. **4** such that the same pins are inserted into the pinholes **30** formed in the resin bag **102** and the pinholes **130** of the cover sheet **10**, respectively, and the cover sheet **10** covers an outer surface of one chamber **108**

among the two chambers.
[0093] The cover sheet **10** has a size where one chamber **110** of the resin bag **102** can be covered, in which the two pinholes **130** are formed. In the example shown in FIG. **4**, the cover sheet **10** has a substantially rectangular shape where the pinhole **130** is formed on both end parts (an upper end part and a lower end part in FIG. **4**) in the vicinity of one side (the right end side in FIG. **4**).
[0094] A method of forming the pinholes **130** in the cover sheet **10**, the shape and size thereof, the distance between the pinholes, and the like are the same as those of the pinholes **30** formed in the resin bag **102**.
[0095] It is preferable that the positions of the pinholes **130** on the cover sheet **10** are set with reference to the end side of the cover sheet **10** on the chamber **108** side during welding to the resin bag **102**. For example, it is preferable that the positions are set such that a straight line formed by connecting the centers of the two pinholes **130** is substantially parallel to the end side of the cover sheet **10** on the chamber **108** side at a predetermined distance. The straight line formed by connecting the centers of the two pinholes **130** may be non-parallel to the end side of the cover sheet **10** on the chamber **108** side.
[0096] In the positioning step, as shown in FIG. **5**, by inserting the same pins into the two pinholes **30** formed in the resin bag **102** and the two pinholes **130** of the cover sheet **10**, respectively, the resin bag **102** and the cover sheet **10** are positioned.
[0097] For example, as shown in FIG. **6**, the resin bag **102** is placed on a placement table **202** where two pins **204** stand while inserting the pins **204** into the two pinholes **30**, respectively, and the cover sheet **10** is placed while inserting the pins **204** into the two pinholes **130**, respectively. As a result, the cover sheet **10** can be appropriately positioned relative to the resin bag **102**.
[0098] In addition, the position of the end side of the cover sheet **10** can be more accurately positioned relative to the weak sealed portion **106** of the resin bag **102**. As a result, a pressing strength required for communication (dissolution before use) of the weak sealed portion **106** that partitions the chamber **110** for accommodating the drug or the like and the chamber **108** for accommodating the liquid drug can be prevented from increasing. This point will be described below.
[0099] As shown in FIG. **6**, the cover sheet **10** may be curled. In this case, it is preferable that the pinholes **30** are formed such that a straight line formed by connecting the two pinholes **30** is substantially parallel to an axial direction of the curling.
Welding Step
[0100] The welding step is performed after the positioning step and is a step of pressing a pressing member to weld the resin bag **102** and the cover sheet **10** in a state where the resin bag **102** and the cover sheet **10** are positioned.
[0101] As shown in FIG. **7**, the resin bag **102** and the cover sheet **10** placed on the placement table **202** by inserting the pins **204** into the pinholes are pressed from the cover sheet **10** side by a pressing member **206** to weld the resin bag **102** and the cover sheet **10**. As in a region indicated by a diagonal line in FIG. **8**, a welded portion **140** where the resin bag **102** and the cover sheet **10** are welded is formed at a position where the strong sealed portion **104** and the weak sealed portion **106** around the chamber **110** overlap each other to cover the chamber **110**. In the example shown in FIG. **8**, the welded portion **140** is formed in a substantially rectangular shape along the end side of the cover sheet **10**. That is, the welded portion **140** is formed in the vicinity of four respective end parts of the rectangular cover sheet **10**.
[0102] Accordingly, the pressing member **206** includes a frame-shaped pressing unit corresponding to the welded portion **140**. In addition, the pressing member **206** includes a heating member that heats the frame-shaped pressing unit, and can thermally weld (heat-seal) the resin bag **102** and the cover sheet **10**.
[0103] In the example shown in FIG. **7**, the pressing member **206** simultaneously welds the entire area of the welded portion **140**, that is, the four sides of the cover sheet **10**.

[0104] In the present invention, a welding method in the welding step is not limited to the method of simultaneously welding the entire area of the welded portion **140**, and the welded portion **140** may be sequentially welded. For example, the welding method may be the method of sequentially welding the welded portion **140** in a direction away from the side of the two pinholes.
[0105] For example, as in the example shown in FIG. **9**, while pressing the resin bag **102** and the cover sheet **10** using a pressing member **206***e* such as a roller having a curved surface, the pressing member **206***e* may be moved in the direction away from the position on the pin **204** side to sequentially weld the region where the welded portion **140** is formed. In this case, a portion of the pressing member **206***e* that comes into contact with the chamber **110** is formed in a recessed shape, and presses only the region where the welded portion **140** is formed.
[0106] Alternatively, the pressing member may be divided into a block shape corresponding to a partial region of the welded portion **140**, and may sequentially weld the resin bag **102** and the cover sheet **10** from the pin **204** side using the divided pressing member.
[0107] For example, in the example shown in FIG. **10**, the pressing member is divided into four pressing members **206***a* to **206***d*. The resin bag **102** and the cover sheet **10** are welded using the pressing member **206***a* on the pin **204** side. Next, the resin bag **102** and the cover sheet **10** are welded using the pressing member **206***b* adjacent to the pressing member **206***a*. Next, the resin bag **102** and the cover sheet **10** are welded using the pressing member **206***c* adjacent to the pressing member **206***b*. Next, the resin bag **102** and the cover sheet **10** are welded using the pressing member **206***d* adjacent to the pressing member **206***c*. As a result, the region where the welded portion **140** is formed is sequentially welded.
[0108] A heating temperature during the welding in the welding step may be appropriately set depending on the kind of the sealant layer, the required bonding strength, the material and thickness of the cover sheet, and the like.
[0109] A pressing strength during the welding in the welding step may be appropriately set depending on the kind of the sealant layer, the required bonding strength, the material and thickness of the cover sheet, and the like.
[0110] Through the above-described steps, the before-use dissolution infusion bag is prepared.
[0111] Here, according to an investigation by the present inventors, it was found that, in order to reduce a pressing strength required for communication of the weak sealed portion (partition member) that partitions the chamber for accommodating the drug or the like and the chamber for accommodating the liquid drug, the cover sheet needs to be bonded to the weak sealed portion with high positional accuracy.
[0112] Specifically, during the communication (dissolution before use) of the weak sealed portion **106** that partitions the chamber **110** for accommodating the drug or the like and the chamber **108** for accommodating the liquid drug, as shown in FIG. **11**, the chamber **108** for accommodating the liquid drug is pressed, the vicinity of the weak sealed portion **106** in the chamber **108** is swelled out and the resin film in the vicinity of the weak sealed portion **106** is pulled in the vertical direction in the drawing such that the weak sealed portion **106** is peeled off and the chambers communicate with each other.
[0113] In this case, it was found that, in a case where the end side of the cover sheet **10** on the chamber **108** side is present closer to the chamber **108** side than the end side of the weak sealed portion **106** on the chamber **108** side, a required pressing strength for the dissolution before use can be reduced.
[0114] This point will be described using FIGS. **12** and **13**.
[0115] Each of FIGS. **12** and **13** is a partially enlarged view showing the vicinity of the weak sealed portion **106** of the before-use dissolution infusion bag. In FIGS. **12** and **13**, the right side in the drawing is the chamber **108**, and the left side is the chamber **110**. As shown in FIGS. **12** and **13**, in the weak sealed portion **106**, the cover sheet **10**, the sealant layer **22**, a resin film **120**, a sealing layer **122**, the resin film **120**, the sealant layer **22**, and the cover sheet **10** are laminated in this

order.
[0116] As shown in FIG. **13**, in a case where the end side of the cover sheet **10** on the chamber **108** side is present closer to the chamber **110** side than the end side of the weak sealed portion **106** on the chamber **108** side, first, a portion where the resin films **120** are weakly scaled is peeled off. Next, a portion where the laminates of the cover sheet **10**, the sealant layer **22**, and the resin film **120** are weakly sealed is peeled off. However, the laminate of the cover sheet **10**, the sealant layer **22**, and the resin film **120** is harder than the resin film **120** and is not likely to be deformed. Therefore, a strength for deforming the laminate during the peeling is required, and a required pressing strength increases.
[0117] On the other hand, as shown in FIG. **12**, in a case where the end side of the cover sheet **10** on the chamber **108** side is present closer to the chamber **110** side than the end side of the weak scaled portion **106** on the chamber **108** side, first, the laminate of the cover sheet **10**, the sealant layer **22**, and the resin film **120** is pulled in the vertical direction to be deformed, and the portion where the laminates are weakly sealed is peeled off. A strength for propagation of the deformation of the cover sheet **10** is lower than a strength for starting the deformation of the cover sheet **10**. Therefore, a required pressing strength can be reduced.
[0118] Accordingly, in order to reduce a pressing strength required for dissolution before use, it is important to appropriately dispose relative positions between the end side of the cover sheet **10** on the chamber **108** side and the end side of the weak sealed portion **106** on the chamber **108** side.
[0119] In order to bond the cover sheet **10** to the weak sealed portion **106** with high accuracy, it is considered to provide a pinhole for positioning in each of the resin bag **102** and the cover sheet **10** such that, by allowing a pin to pass through the pinholes, the resin bag **102** (weak sealed portion **106**) and the cover sheet **10** are positioned with high accuracy.
[0120] However, the resin bag **102** includes a strong scaled portion **104** that bonds the peripheral ends with a high bonding strength and a weak sealed portion **106** that is bonded with a weaker bonding strength than the strong sealed portion **104**. Therefore, a form deformed by thermal contraction and/or thermal expansion due to heat or the like during sterilization cannot be expected. Therefore, it was found that in a case where the pinhole **130** for positioning is formed before sterilization, the shape and/or size of the pinhole **130** is deformed and the accuracy cannot be ensured.
[0121] In addition, the entire resin bag **102** is bent due to heat during sterilization. In addition, unpredictable deformation such as curling may be present in the cover sheet **10**, and thus it is difficult to accurately fix the cover sheet **10** on a plane.
[0122] Therefore, it was found that, simply even with the configuration of providing a pinhole for positioning in each of the resin bag **102** and the cover sheet **10** such that, by allowing a pin **204** to pass through the pinholes, the resin bag **102** (weak sealed portion **106**) and the cover sheet **10** are positioned with high accuracy, it is difficult to position the cover sheet **10** relative to the weak sealed portion **106** with high positional accuracy.
[0123] As a result, it was found that there is a problem in that a pressing strength required for communication (dissolution before use) of the weak sealed portion **106** that partitions the chamber **110** for accommodating the drug or the like and the chamber **108** for accommodating the liquid drug increases.
[0124] On the other hand, in the manufacturing method according to the embodiment of the present invention, the pinhole forming step of providing the pinhole **130** in the resin bag **102** is performed after the sterilization step, and the two pinholes **130** formed in the pinhole forming step are formed such that a straight line formed by connecting the centers of the two pinholes **130** is positioned on the weak sealed portion **106**. As a result, the shape and/or size of the pinhole **130** can be prevented from being deformed, the pinhole **130** can be positioned relative to the resin bag **102** deformed due to heat during sterilization with high accuracy. In addition, since the pinhole **130** is formed in the vicinity of the weak sealed portion **106**, the pinhole **130** can be positioned relative to the end side

of the weak sealed portion **106** on the chamber **108** side with high accuracy. Accordingly, in a case where the cover sheet **10** is welded, a positional relationship between the end side of the cover sheet **10** on the chamber **108** side and the end side of the weak sealed portion **106** on the chamber **108** side can be determined with high accuracy. Therefore, as shown in FIG. **12**, the configuration where the end side of the cover sheet **10** on the chamber **108** side is present closer to the chamber **110** side than the end side of the weak sealed portion **106** on the chamber **108** side can be reliably formed. Accordingly, a before-use dissolution infusion bag having a low pressing strength required for dissolution before use can be prepared.

[0125] In the manufacturing method according to the embodiment of the present invention, in a case where the two cover sheets **10** are welded to the resin bag **102**, at least one of the cover sheets **10** may be welded to the resin bag **102** using the manufacturing method, and it is preferable that both of the two cover sheets **10** are welded to the resin bag **102** using the manufacturing method. In addition, in a case where the two cover sheets **10** are welded to the resin bag **102** using the manufacturing method, the positioning step and the welding step may be performed on each of the two cover sheets **10** to sequentially weld each of the two cover sheets **10**, or the positioning step and the welding step may be simultaneously performed on the two cover sheets **10** to simultaneously weld the two cover sheets **10**.

[0126] Hereinbefore, the method of manufacturing a before-use dissolution infusion bag according to the embodiment of the present invention has been described in detail. However, the present invention is not limited to the above-described aspects and various improvements and changes may be made within a range not departing from the scope of the present invention.

Explanation of References

[0127] **10**: cover sheet [0128] **22**: sealant layer [0129] **30**: pinhole [0130] **100**: before-use dissolution infusion bag [0131] **102**: resin bag (bag body, infusion bag) [0132] **104**: strong sealed portion [0133] **106**: weak sealed portion [0134] **108**, **110**: chamber [0135] **120**: resin film [0136] **122**: sealing layer [0137] **130**: pinhole [0138] **140**: welded portion [0139] **202**: placement table [0140] **204**: pin [0141] **206**, **206***a* to **206***e*: pressing member

Claims

1. A method of manufacturing a before-use dissolution infusion bag, the method comprising: a sterilization step of sterilizing an infusion bag including two chambers for accommodating drugs and a weak sealed portion for isolating the two chambers from each other such that the two chambers are communicable with each other; a pinhole forming step of providing two pinholes in a strong sealed portion for isolating the chambers of the infusion bag and an outside from each other after the sterilization step; a positioning step of positioning the infusion bag and a cover sheet having pinholes such that the same pins are inserted into the pinholes formed in the infusion bag and the pinholes of the cover sheet, respectively, and the cover sheet covers an outer surface of one chamber among the two chambers; and a welding step of pressing a pressing member to weld the infusion bag and the cover sheet in a state where the infusion bag and the cover sheet are positioned, wherein a straight line formed by connecting centers of the two pinholes formed in the infusion bag is positioned on the weak sealed portion.

2. The method of manufacturing a before-use dissolution infusion bag according to claim 1, wherein in the welding step, an entire area of a welded portion surrounding the one chamber is simultaneously welded.

3. The method of manufacturing a before-use dissolution infusion bag according to claim 1, wherein in the welding step, the infusion bag and the cover sheet are sequentially welded from a side of the two pinholes.

4. The method of manufacturing a before-use dissolution infusion bag according to claim 3, wherein in the welding step, the infusion bag and the cover sheet are sequentially welded from the

side of the two pinholes using the pressing member having a curved surface.

5. The method of manufacturing a before-use dissolution infusion bag according to claim 3, wherein in the welding step, the infusion bag and the cover sheet are sequentially welded from the side of the two pinholes using the pressing member that is divided for each of blocks.