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EP 2 568 950 B1

Description

[0001] The present invention refers to a flexible single or multiple chamber bag for storing medical products comprising at least one chamber.

[0002] In the pharmaceutical industry and especially in the field of perfusion solutions, impermeable flexible bags are extensively used. Such bags or containers are prepared from polymerized materials which have to meet a wide variety of requirements. Thus, in particular, gas and vapor tightness, transparency, printability and inertness towards the substances they contain, are of essential importance as well as the handling by the nurse administering the medical products to the patient. The substances contained in the containers or bags essentially consist of salts and solutions thereof, carbohydrates, amino acids and lipids. They are usually employed in single or multicompartment bags, the individual compartments or chambers being filled with one or different components.

[0003] EP 0 295 204 B1 describes a container for medical use, in particular a container for infusions consisting of an envelope made of a flexible, homogeneous, polymerized material which is divided into three compartments, separated from each other by leaktight welds of the envelope material and each of said compartments is provided with an occluded passage which can be opened deliberately to enable the contents of the part of the interior space to flow into another one. In use the container may be affixed by an eyebolt having the typical shape of such eyebolt for hanging blister packs to a peg. A proper hanging of the heavy container requires stiffening of the flap around the eyebolt and causes handling disadvantages.

[0004] EP 1 011 605 B2 relates to a flexible plastic container (1) for the spatially separated storage and, optionally, selective sterilization of the ingredients of preparations of parenteral or enteral use, consisting of only three compartments. Said document simply uses a circular eyebolt in the area of the top of said bag in use and a second eyebolt located within the sealed weld separating the upper chamber from the lower chamber. The use of such second eyebolt is possible due to the use of the special connecting means made as breakable valves.

[0005] WO 2007/037793 A1 relates to a multiple chamber container for separately storing components of a parenteral nutritional formulation. The multiple chamber container may include frangible barriers, preferably peelable seals separating the chambers from each other. The container preferably facilitates the selective activation of the peelable seals to permit the admixing of less than all the separately stored components. The container may include a hanger flap extending from the top end of the container towards the bottom end of substantially greater distance relative to the at least one additional chamber than the lateral chambers. At the top end of the container, in particular opposite end where the administration port(s) are located, there is provided a hanger portion being a flap having a centrally located hole for hanging the container. The flap defines a border of the upper end of all the chambers. The central portion of the hanger flap extends a substantial distance towards the bottom end of the container, in particular about one-fourth the longitudinal length L of the container. In particular, the flap extends a greater distance towards the bottom end at least at the central chamber and can also extend a greater distance towards the bottom end at the central chamber and at one of the other chambers. This extra extension of the flap with respect to center chamber results in said chamber having a shorter longitudinal length than the longitudinal length of lateral or side end chambers.

[0006] WO9003775 discloses a flexible bag comprising a hanger flap extending from the top end of the bag.

[0007] Thus, it is the aim of the present invention to simplify the handling of a flexible single or multiple chamber bag for storing medical products and in particular to improve the use thereof by the nurse when administering the medical products to the patient.

[0008] The above objects of the invention are met in a first embodiment of the invention by a flexible single or multiple chamber bag 10 for storing medical products comprising a hanger flap 11 extending from the top end of said bag, which is characterized in that said hanger flap 11 contains

a) two mirror invented circular cuttings 1 and 2 of an angle of 145° to 180°, wherein one end of each of said cuttings 1 and 2 is spaced apart by a connecting cutting 3 being essentially being straight-lined having a length of 4 times to 10 times the radius of said circular cuttings 1,2 and

b) two mirror invented circular cuttings 4 and 5 of an angle of 180° to 270°, having a radius of 0,3 to 0,7 of the radius of said cuttings 1 and 2, wherein one end of each of said cuttings 4 and 5 is spaced apart by a connecting cutting 6 having the shape of the letter "U",

c) wherein said cuttings 1, 2, 4, and 5 are positioned along a common mirror symmetry axis through the centres of said cuttings 3 and 6 and the basis of said letter "U" and

d), the distance of the center of said cutting 3 and the basis of said letter "U" corresponds to the 0,5 to 1,5 times the radius of said cuttings 1 and 2.

[0009] Due to the specific structure of the hanger flap of a single or multiple chamber bag, the object of the invention as outlined above is met.

[0010] Fig. 1 in detail shows a flexible three chamber bag 10 according to the present invention, which is intended for storing medical products. It goes without saying that the number of chambers and the specific shape is illustrative only. The inventive concept of the hanger flap may be transformed to all kinds of single or multiple chamber bags. The multiple chamber bag according to

the present invention in Fig. 1 contains three adjacent chambers.

[0011] Selected seams or welds within the circumferential weld 7 may be peelable when applying pressure on the bag 10 independent from the technique of the nurse by applying pressure or by rolling the multiple chamber bag 10.

[0012] The single or multichamber bag according to the present invention is made of a flexible polymeric film having a region with a higher melting point designated as its outside and having a region with a lower melting point designated as its sealing inside, which can be sealed together by means of conventional welding tools to permanent or peelable seams. It is to be understood that the inner region is intended to face the stored components and can form both, permanent seams and different peelable seams when subjected to different welding conditions or operations. It is in particular preferred that the film is made of at least two different polymer layers wherein the inside layer is a sealant layer being capable of forming both, permanent seams and peelable seams when subjected to welding at different temperatures. Polymeric materials providing said features are known from in particular the prior art.

[0013] The bag 10 according to the present invention comprises a hanger flap 11 extending from the top end of said bag next to the upper chamber in particular within the circumferential weld 7.

[0014] Fig. 2 is a detailed view of the hanger flap 11 according to the present invention. The hanger flap 11 contains two different cuttings which are separated to each other and are intended to fulfil different purposes. The upper cutting next to the outer edge of the circumferential weld contains three different parts 1, 2, 3 having a size and shape for the insertion of at least four or five fingers of a standard hand of a nurse. Two mirror inverted circular cuttings 1 and 2 describe an angle of 145° to 180°, wherein one said cuttings 1 and 2 are spaced apart by a connecting cutting 3 being essentially straight lined. Preferably, the connecting cutting 3 has the shape of a palm and connects the outer circular cuttings 1 and 2. The radius of the circular cuttings 1 and 2 is adapted to the average size fitting a palm and thus compares to the average size of a usual finger of a hand. The distance between the circular cuttings 1 and 2 compares to the average width of a standard palm allowing the insertion of at least four or five fingers of a standard hand. Thus, the length of the cutting 3 according to present invention preferably is four times to ten times the radius of said circular cuttings.

[0015] Additional mirror inverted circular cuttings 4 and 5 are located symmetrically to the upper cuttings 1,2,3. Said cuttings 4 and 5 are spaced apart but connected by a connecting cutting 6 having the shape of the letter "U" like a nose. The purpose for this specific double eyebolt allows a proper hanging of the bag to an appropriate pole or peg during the administration of the content of the bag via a port at the lower end of the bag to the patient. Two mirror inverted circular cuttings 4 and 5 each of an angle of 180° to 270° having a smaller radius than said cuttings 1 and 2 are connected via a connecting cutting 6. The purpose of the connecting cutting 6 with the shape of the letter "U" is to bear the load of the filled bag. Due to this specific shape no additional stiffening of the hanger flap is required.

[0016] The upper cuttings 1,2 and the lower cuttings 4, 5 are positioned along a common mirror symmetry axis through the center of said cuttings 3 and 6.

[0017] The distance of the upper cuttings 1,2,3 to the lower cuttings 4,5,6 is determined by the stability of the foils of the bag. In case said distance is too small rupture may take place destroying the lower cuttings 4,5,6. On the other hand, in case the distance of the upper cuttings 1,2,3 to the lower cuttings 4,5,6 is too large the overall size of the hanger flap becomes too large causing disadvantages during the use in the hospital. In a preferred embodiment of the present invention, the flexible single or multiple chamber bag 10 contains two, three, four or more chambers whereby a three or four chamber bag is in particularly preferred.

[0018] As mentioned above, the bag 10 according to the present invention in particular contains medical products, such as solutions, emulsions, suspensions and/or dispersions suitable for parenteral or enteral nutrition of patients.

[0019] In particular, the chamber partially separating an upper chamber and a lower chamber contains a fat emulsion. Accordingly, the upper chamber contains a carbohydrate solution and the lower chamber contains an amino acid solution. The features of the bag as described above ensure a rapid mixing and complete emulsification of all contents of the container for the administration of the content to the patient via a port at the lower end of the bag.

Claims

1. A flexible single or multiple chamber bag (10) for storing medical products comprising a hanger flap (11) extending from the top end of said bag, **characterized in that** said flap (11) contains

   a) first two mirror inverted circular cuttings (1, 2) of an angle of 145° to 180°, wherein one end of each of said cuttings (1, 2) is spaced apart by a first connecting cutting (3) being essentially being straight-lined having a length of 4 times to 10 times the radius of said first circular cuttings (1,2) and

   b) second two mirror inverted circular cuttings (4, 5) of an angle of 180° to 270° having a radius of 0,3 to 0,7 of the radius of said first cuttings ((1) ,(2)), wherein one end of each of said second cuttings ((4), (5)) is spaced apart by a second connecting cutting (6) having the shape of

the letter "U",

c) wherein said first and second mirror inverted circular cuttings ((1), (2), (4), (5)) are positioned along a common mirror symmetry axis through the centers of said first and second connecting cuttings ((3) ,(6)) and the basis of said letter "U" and

d), the distance of the center of said first connecting cutting (3) and the basis of said letter "U" corresponds to the 0,5 to 1,5 times the radius of said first mirror invented circular cuttings ((1), (2))

2. The flexible bag (10) according to claim 1, **characterized in that** the first and second mirror inverted circular ((1), (2), (4) , (5)) essentially terminate to the direction of the bottom of the bag when in use.

3. The flexible bag according to claim 1 or 2, **characterized in that** the overall length of first two mirror inverted cuttings and first connecting cutting ((1), (2), (3)) is sufficient for holding four fingers of a standard hand.

Patentansprüche

1. Flexibler Ein- oder Mehrkammerbeutel (10) zur Aufbewahrung medizinischer Produkte, der eine Aufhängelasche (11) umfasst, die sich ausgehend vom oberen Ende des Beutels erstreckt, **dadurch gekennzeichnet, dass** die Lasche (11) Folgendes enthält:

a) zwei erste, spiegelbildlich zueinander angeordnete kreisbogenförmige Einschnitte (1, 2) mit einem Winkel von 145° bis 180°, wobei jeweils ein Ende der Einschnitte (1, 2) durch einen ersten Verbindungseinschnitt (3), der im Wesentlichen gerade ist und eine Länge vom Vierfachen bis Zehnfachen des Radius der ersten kreisbogenförmigen Einschnitte (1, 2) aufweist, voneinander beabstandet sind; und

b) zwei zweite, spiegelbildlich zueinander angeordnete kreisbogenförmige Einschnitte (4, 5) mit einem Winkel von 180° bis 270°, die einen Radius vom 0,3-fachen bis 0,7-fachen des Radius der ersten Einschnitte (1, 2) aufweisen, wobei jeweils ein Ende der zweiten Einschnitte (4, 5) durch einen zweiten Verbindungseinschnitt (6), der die Form des Buchstabens "U" aufweist, voneinander beabstandet sind;

c) wobei die ersten und zweiten, spiegelbildlich zueinander angeordneten kreisbogenförmigen Einschnitte (1, 2, 4, 5) entlang einer gemeinsamen Spiegelsymmetrieachse durch die Zentren des ersten und des zweiten Verbindungseinschnitts (3, 6) und die Basis des Buchstabens "U" positioniert sind; und

d) der Abstand zwischen dem Zentrum des ersten Verbindungseinschnitts (3) und der Basis des Buchstabens "U" dem 0,5- bis 1,5-fachen des Radius der ersten, spiegelbildlich zueinander angeordneten kreisbogenförmigen Einschnitte (1, 2) entspricht.

2. Flexibler Beutel (10) gemäß Anspruch 1, **dadurch gekennzeichnet, dass** die ersten und zweiten, spiegelbildlich zueinander angeordneten kreisbogenförmigen Einschnitte (1, 2, 4, 5) im Wesentlichen in die Richtung zum Boden des Beutels hin auslaufen, wenn sie in Verwendung sind.

3. Flexibler Beutel gemäß Anspruch 1 oder 2, **dadurch gekennzeichnet, dass** die Gesamtlänge der ersten zwei spiegelbildlich zueinander angeordneten Einschnitte und des ersten Verbindungseinschnitts (1, 2, 3) ausreichend ist; um vier Finger einer normal großen Hand unterzubringen.

Revendications

1. Sac flexible à chambre unique ou à chambres multiples (10) pour stocker des produits médicaux, comprenant une languette d'accrochage (11) s'étendant à partir de l'extrémité supérieure du sac, **caractérisé en ce que** ladite languette (11) contient

a) deux premières incisions circulaires, symétriques en miroir (1, 2), formant un angle de 145° à 180°, dans lequel une extrémité de chacune desdites incisions (1, 2) est espacée par une première incision de connexion (3) étant essentiellement droite et ayant une longueur de 4 fois à 10 fois le rayon desdites premières incisions circulaires (1, 2), et

b) deux secondes incisions circulaires, symétriques en miroir (4, 5), formant un angle de 180° à 270°, ayant un rayon de 0,3 à 0,7 fois le rayon desdites premières incisions (1, 2), dans lequel une extrémité de chacune desdites secondes incisions (4, 5) est espacée par une seconde incision de connexion (6) ayant la forme de la lettre "U",

c) dans lequel lesdites premières et secondes incisions circulaires, symétriques en miroir (1, 2, 4, 5), se situent le long d'un axe de symétrie commun à travers des centres desdites premières et secondes incisions de connexion (3, 6) et la base de ladite lettre "U", et

d) la distance entre le centre de ladite première incision de connexion (3) et la base de ladite lettre "U" est 0,5 à 1,5 fois le rayon desdites premières incisions circulaires, symétriques en miroir (1, 2).

2. Sac flexible (10) selon la revendication 1, **caractérisé en ce que** lesdites premières et secondes incisions circulaires, symétriques en miroir (1, 2, 4, 5), aboutissent essentiellement vers la direction du fond du sac durant son utilisation.

3. Sac flexible selon la revendication 1 ou 2, **caractérisé en ce que** la longueur totale des deux premières incisions, symétriques en miroir, et la première incision de connexion (1, 2, 3) est suffisante pour accommoder quatre doigts d'une main de taille normale.

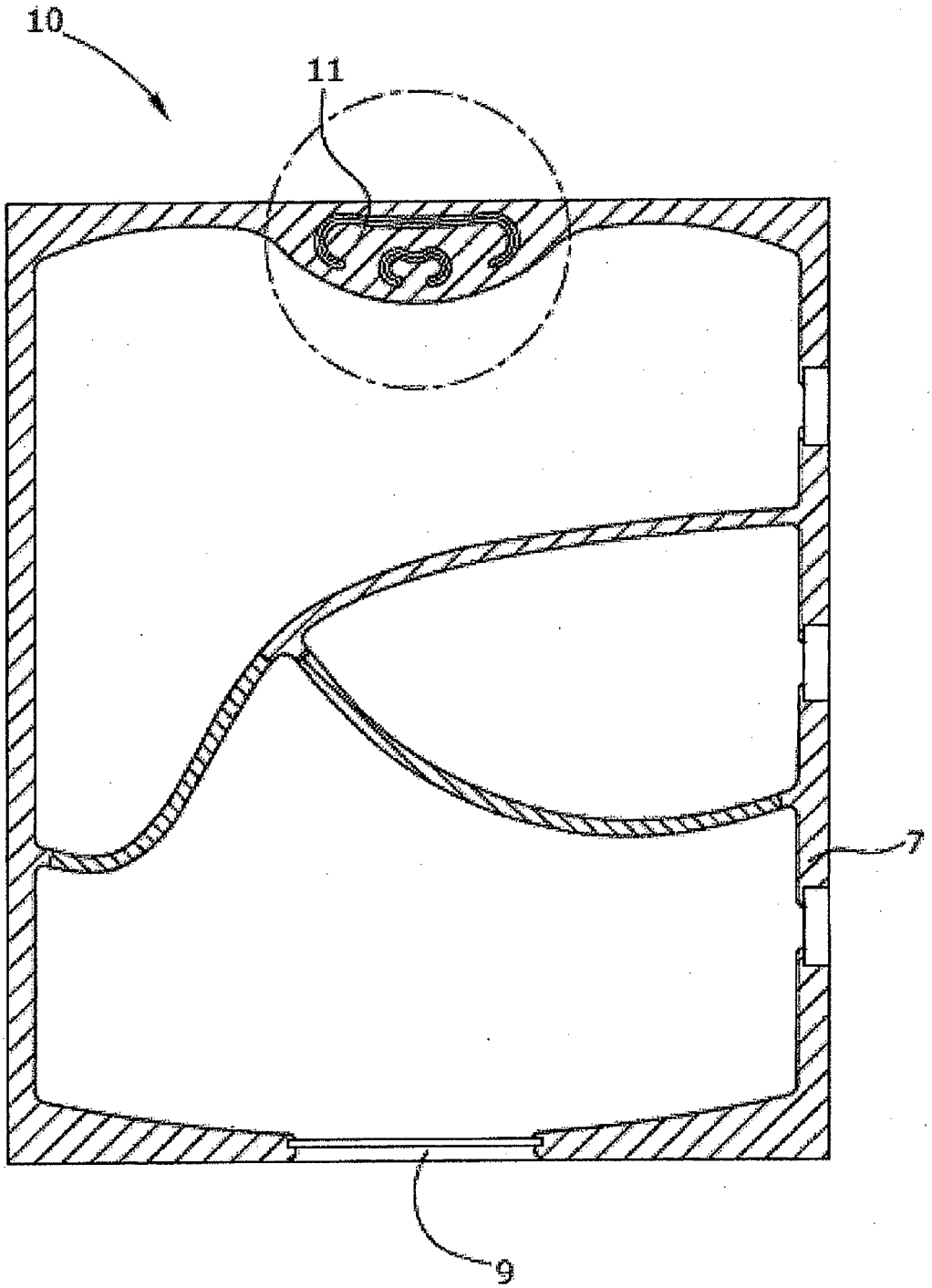


Fig.1

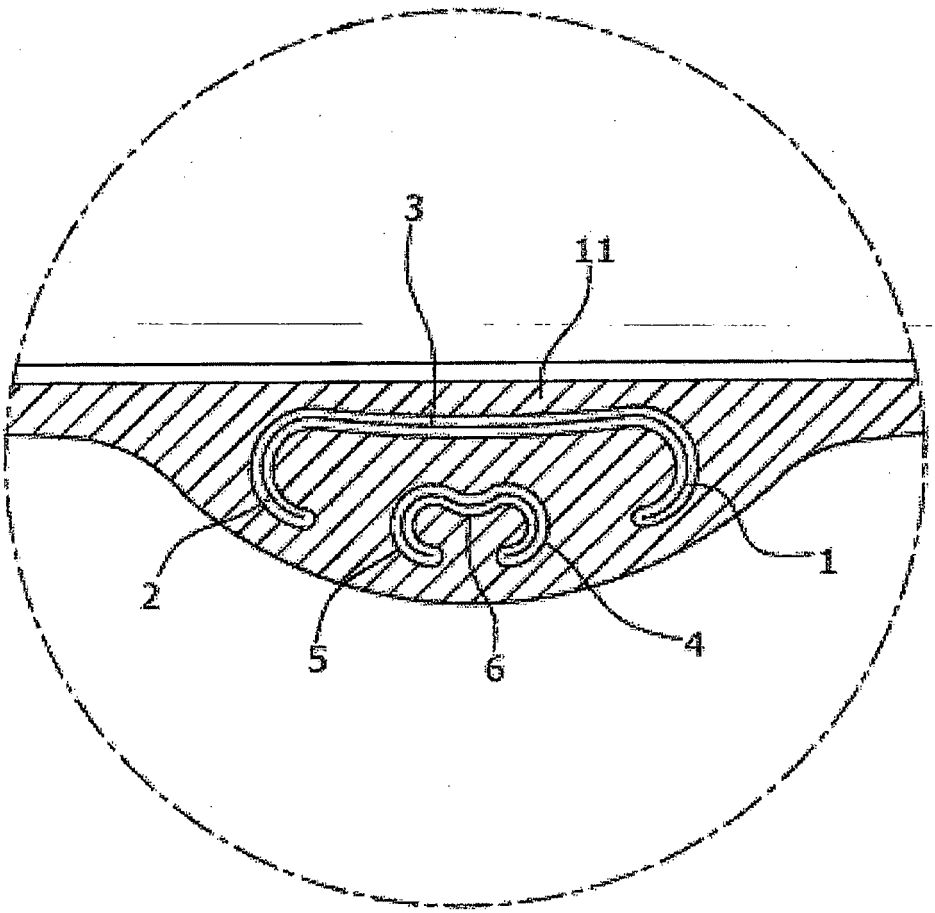


Fig. 2

REFERENCES CITED IN THE DESCRIPTION

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- WO 9003775 A **[0006]**