(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) Publication number: **0 161 231**
A2

(12) EUROPEAN PATENT APPLICATION

(21) Application number: **85850155.4**

(51) Int. Cl.⁴: **A 61 J 1/00**

(22) Date of filing: **03.05.85**

(30) Priority: **09.05.84 SE 8402509**

(43) Date of publication of application:
13.11.85 Bulletin 85/46

(84) Designated Contracting States:
AT BE CH DE FR GB IT LI LU NL

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(54) A container device and a method for manufacturing of the device.

(57) A flexible container device, preferably for medical use, comprising a container and a hose-shaped connector.

The container, which is a sterile container, has a tearable-away first cover layer (11) over locations (12) for connecting the hose. The hose, which is sterilized, has an adhesive surface covered by a second tearable-away cover layer (19). Inside the hose there is a puncturing element (21) manoeuvreable from the other end of the hose for puncturing the container under a maintained sterile environment after the connector has been mounted.

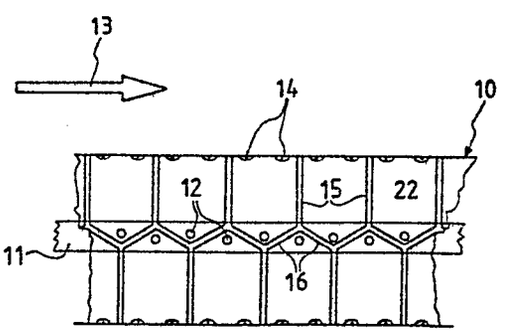

FIG. 1

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A CONTAINER DEVICE AND A METHOD FOR MANUFACTURING OF THE DEVICE.

The present invention relates to a flexible container and a method for manufacturing of the container. More precisely, the invention relates to a container device comprising a container and a hose type connector. The container device is designed for being used in medical applications. As an example of a broad field of use the dialysis method called peritoneal dialysis may be referred to, i.e. a dialysis carried out by using the belly membrane.

Such a dialysis represents one of several methods of treatment for purifying blood and is based on the use of the belly membrane as a blood filter. The technique is based on filling the belly cavity by a liquid and then using the belly membrane as a filter for the blood. So called pouch dialysis represents one possibility.

Today there exist some flexible container devices, pouches, comprising a softened PVC pouch provided with a connector hose. The pouches are filled by a liquid (for instance an infusion liquid) and are packed in an outer pouch which is put under light "vaccum". Thereafter such packages are batch-wise put into an autoclave for being retorted.

There are several reasons for eliminating the arrangement comprising the outer pouch and the cumbersome handling of this prior art system. Provided that the sources of error may be eliminated in a reliable way it would be desirable to hand over some assembling work to the patient if this would imply a better over-all economy.

The object of the present invention is to take care of the problem and offer a system that is an optimum.

Basically the invention starts out from a known sterile system where a liquid is filled into a hose formed from a web of a flexible material, the hose-shaped web with

contents is sterilized in-line, the hose-shaped web is welded and individual flexible pouches punched out from the welded hose-shaped web.

Starting out from this the present invention provides a flexible container device forming a sterile system comprising a container and a hose-shaped connector. The container device is characterized in that the container has a tearable-away first cover layer, for instance a tape, arranged over at least one sterile location of connection of at least one hose, that one end of the hose has a second cover layer placed over a sterile device for mounting the hose onto the container, and that an external gripping device is arranged for being available from the other end of the hose and operatively connected to a puncturing device inside the hose for puncturing the container after the hose has been mounted onto the container, thereby maintaining a generally sterile condition of the system.

Starting out from this specific structure the container comprises a container formed from a flexible hose-shaped web having a first cover layer applied thereon.

Preferably, the first cover layer is arranged as a strip of material extending across the direction of lateral weld seams of the hose-shaped web forming side weld seams.

In order to provide a user oriented easy handling, the hose-shaped connector preferably is an easy bendable structure, and the puncturing device comprises a knife-shaped blade having a cutting edge supported by a grip device at a certain distance from the other end of the hose.

In a preferred embodiment the second end of the hose-shaped connector is terminated by a plate, one side of which has a surface that is adhesive relative the container and covered by said second cover layer in the unassembled state.

The invention also provides a method of manufacturing a container for a flexible container device comprising a container and a hose-shaped connector. The method is characterized in that a flexible web is provided with a

removable cover layer, at least in regions thereof designed for forming locations for connecting a hose, that the web is given hose-shape, that the web is filled by a liquid in such an amount that individual pouch-shaped filled containers may be obtained, that the web, the cover layer and the liquid are sterilized, that the web is welded to form individual container, and that individual containers are punched out in the regions of the weld seams.

In the preferred embodiment the sterilizing operation is carried out in-line with the filling.

When carrying out the welding there are preferably also formed holes in the container for supporting it.

One embodiment of the invention will now be described by reference to the accompanying drawing, where

Figure 1 schematically shows a set of individual containers formed in a hose-shaped web, and

Figure 2 schematically shows a hose device provided with means for puncturing individual containers.

The hose 10 in Figure 1 is a hose of a flexible material having good steam and gas barrier properties and being heat resistant for sterilizing operations up to a temperature of around 120 - 150°C. There are several suitable laminates, known per se, based on for instance two or more of the following materials, polypropylene, preferably HD-polypropylene, polyvinylidienchloride, polyamide and metal foil, possibly in combination with a suitable sealing layer. A protecting, but easy tearable- away layer, in the present case a tearable-away strip, tape 11, is attached in the longitudinal direction of the hose. Tape 11 is attached to the hose such that locations 12 for connecting a hose-shaped connector (Figure 2) are covered. As such, there is no requirement that the tape should be an integral strip in the longitudinal direction of the hose. The basic requirement is that each location of a connecting hose, one or several locations for each individual container, is covered by a protective layer.

The arrow 13 indicates the transport direction of the hose. The hose is fed from a known apparatus for forming a

web into a hose, filling the hose, sterilizing (externally and internally) the hose and the contents thereof, forming of individual flexible containers and separating such containers. The cover strip 11, integral or comprising individual pieces, being shown in Figure 1 on the hose, is attached thereto at the input side of the filling and sterilizing device. The locations 12 of connection the hose shown in Figure 1 may be pre-marked onto the hose, possibly by weakening lines, so that there will be no doubt as where to mount the hose.

In Figure 1 there is also shown how the connector ends are formed and welded into a zic-zac pattern in a material saving manner. There are also shown holes 14 for supporting the container in the bottom region of each individual container. Preferably such holes are formed when the weld seams 15 and 16 are realized. In the present case such weld seams indicate two adjacent rows of containers, but it is of course realized that the weld seams and the individual containers may be obtained in several different ways..

In Figure 2 the hose 17 consists of a soft resilient material, for instance softened PVC and has a plate 18 attached thereto at the mounting end. There is an adhesive coating on the mounting side of the plate and such adhesive coating is covered by a tearable-away strip 19.

At the other end of the hose 17 there is a "capsule like" grip device 23 that is removably attached to the hose, for instance by threads. The grip device is provided with a support 20 for a puncturing device 21, for instance a knife type of edge or punch. The support 20 is dimen- sioned such that it places the edge 21 at a certain distance from the plate 18.

The arrangement comprising the hose, the attachment plate and the knife is delivered as a sterile unit in a sterile container, for instance a pouch.

The containers 22 are delivered filled by a liquid, for instance an infusion liquid and are provided with a cover strip 11 over the location or locations of connecting the hose.

The mounting of the plate 18 at the location 12 of connection is carried out immediately after removing the strip 11 and of course the strip 19. This means a nearly "unbroken" sterile environment for the pouch 22 and hose 17.

Maintaining this sterile environment the pouch thereafter is punctured by means of the knife 21. The grip portion 23 and the knife are removed and the hose is immediately connected to the input terminal of the body, in the present case the belly cavity.

CLAIMS

1. A flexible container device forming a sterile system, comprising a container (22) and a hose-shaped connector (17), c h a r a c t e r i z e d in that the container is provided with a tearable-away first cover layer (11), for instance a tape, arranged over at least one sterile location (12) of connection of at least one hose (17), that one end of the hose has a second cover layer (19) covering a sterile device (18) for assembling the hose onto the container, and in that a grip device (23) is arranged for being available from the outside at the other end of the hose and operatively connected to a puncturing device (21) inside the hose for puncturing the container after the hose has been mounted to the container, thereby maintaining a generally sterile condition of the system.

2. A container device according to claim 1, c h a r a c t e r i z e d in that the container comprises a container formed from a flexible hose-shaped web having a first cover layer (11) applied thereon.

3. A container device according to claim 2, c h a r a c t e r i z e d in that the first cover layer (11) is a strip across the direction of lateral weld seams (15) in the hose-shaped web forming side weld seams of the container.

4. A container device according to claim 1, c h a r a c t e r i z e d in that the connector hose (17) is of an easy bendable construction, and the puncturing device (21) comprises a knife formed blade having a cutting edge supported by a support device at a certain distance from the other end of the hose.

5. A container device according to claim 4, c h a r a c t e r i z e d in that the other end of the connector hose is terminated by a plate (18), one side of which has an adhesive surface relative the container and is covered by said other cover layer in an unassembled state.

6. A method for manufacturing a container for a flexible container device, comprising a container and a hose-shaped connector element according to anyone or any of the preceding claims, c h a r a c t e r i z e d in that a flexible web is provided with a tearable-away cover layer, at least in regions thereof designed for forming locations for connecting a hose, that the web is given hose-shape, that the web is filled by a liquid in such an amount that individual pouch-shaped filled containers may be obtained, that the web, the cover layer and the liquid are sterilized, that the web is welded for forming individual containers, and that individual containers are punched out along the extension of said weld seams.

7. A method according to claim 6, c h a r a c t e r i z e d in that the sterilizing operation is carried out in-line with filling the containers.

8. A method according to claim 7, c h a r a c t e r i z e d in that the welding operation also comprises forming of holes in the pouch for supporting the pouch.

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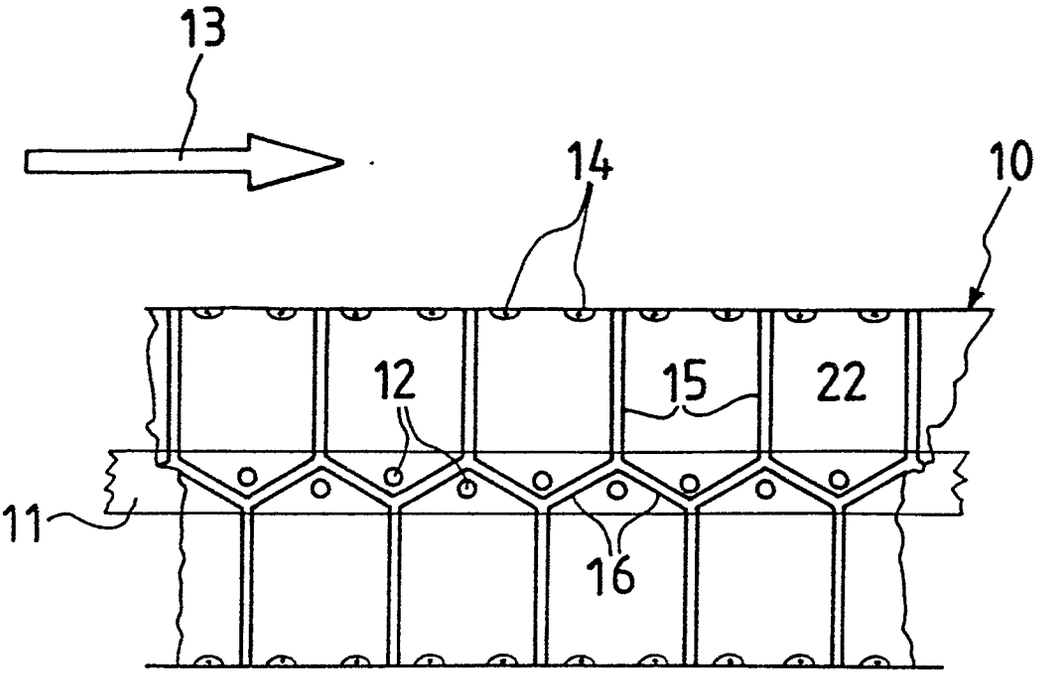

FIG. 1

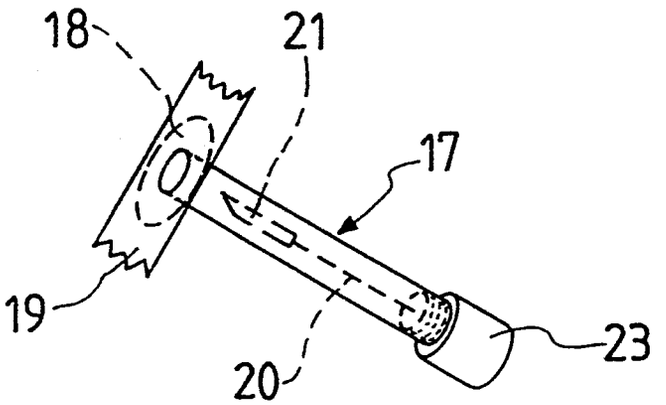

FIG. 2