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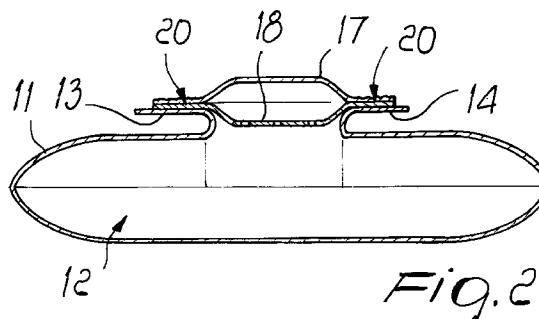
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(54) **Improved pouch package which can be sterilised with a sterilising-gas process**

(57) The present invention relates to an improved pouch package which can be sterilized with a sterilizing-gas method. The package (10) is of the pouch type made of heat-sealable plastics and comprises at least one portion (16) which is permeable to gases and impermeable to germs, bacteria or the like. The portion is a multilayer element obtained by means of at least one medical-grade paper (17) and a backing film (18).



EP 0 861 790 A1

Description

The present invention relates to an improved pouch package which can be sterilized with a sterilizing-gas process.

Pouch packages made of heat-seal able plastics are currently provided in the packaging of disposable medical products, such as for example medical devices and the like.

The plastic material used is generally constituted by a polyethylene film.

These applications typically use machines which, starting from a film of preset width, automatically fold said film and bond it longitudinally; once the medical device to be packaged has been inserted, said machines produce thermal bonds at the ends and then divide each resulting pouch from the next one by means of a transverse cut.

Particularly for all medical devices and packages that cannot be sterilized by gamma radiation, after completing the heat-sealing of the flaps of the package, the package is placed inside a chamber in which the sterilizing gas, such as for example ethylene oxide, is introduced; said gas is meant to sterilize both the inside of the package and the device contained therein.

The sterilizing gas must be extracted after a preset period at the end of its sterilizing action.

The technical problem that arises is linked to the extraction of the gas from the sealed pouch.

Expensive and complicated methods are currently used to extract the gas owing to the need to keep the inside of the package and its contents sterile.

In practice, packages are widely used which are obtained from a plastic sheet which is folded and heat-sealed longitudinally with a strip of medical-grade paper.

This strip has a structure which allows it to be easily crossed by the sterilizing gas and to form a barrier against the passage of germs and bacteria.

The sterilizing gas is then introduced in the package thus produced, in a chamber provided specifically for this function; said gas disinfests both the product and the inside of the package, i.e., the environment in which said product must be preserved.

Once the sterilizing action has ended, the gas, which is extracted by vacuum, can exit through the strip of medical-grade paper.

This package, however, entails several drawbacks.

First of all, the medical-grade paper thermally bonds with the polyethylene sheet with difficulty.

This is partly solved by using a thermal bonding lacquer at the portions to be bonded, which thermal bonding lacquer requires however some time to allow fixing to become effective.

In practice, therefore, during this time the paper and the polyethylene sheet cannot be processed or handled, and this leads to a slowing of final production and makes it impossible to use existing equipment and

known methods.

The thermal bonding lacquer in fact does not allow a high production rate and has a limited strength while hot, consequently making it very likely that the bonded regions will open if they are handled.

The thermal bonding lacquer does not ensure intact bonding and therefore the danger arises that the poorly bonded portions may connect the inside of the package to the outside, making the gas sterilization process useless.

Moreover, the thermal bonding lacquer is based on solvents including toluene, which are highly toxic substances.

Medical-grade paper is often subject to tearing, i.e., it does not have mechanical characteristics sufficient to allow it to withstand traction.

The aim of the present invention is to provide an improved pouch package which eliminates or significantly reduces the drawbacks mentioned above of conventional types.

Within the scope of this aim, a particular object of the present invention is to provide an improved sterilizable pouch package which can be obtained by using conventional equipment and in compliance with the production level allowed by said equipment.

Another important object of the present invention is to provide an improved sterilizable pouch package whose mechanical characteristics are suitable to make it effectively withstand the stresses that would lead to unintended breakages.

Another important object of the present invention is to provide an improved sterilizable pouch package which can be obtained at an extremely competitive cost.

Another object of the present invention is to provide an improved sterilizable pouch package which does not use toxic and noxious substances.

This aim, these objects and others which will become apparent hereinafter are achieved by a package of the sterilizable pouch type made of a heat-sealable plastic film, characterized in that at least one portion thereof is permeable to gases and impermeable to germs, bacteria or the like, said portion being a multi-layer element obtained by means of at least one medical-grade paper and a backing film.

Further characteristics and advantages of the present invention will become apparent from the detailed description of an embodiment thereof, illustrated only by way of non-limitative example in the accompanying drawings, wherein:

figure 1 is a perspective view of an improved sterilizable pouch package according to the invention; figure 2 is a transverse sectional view of an improved sterilizable pouch package according to the invention; figure 3 is a perspective view of a part of an improved sterilizable pouch package according to the invention.

With reference to the above figures, an improved sterilizable pouch package according to the invention is generally designated by the reference numeral 10 and is constituted by a film 11 made of heat-sealable plastics, which constitutes substantially a pouch-like container 12 inside which a medical device, such as for example a syringe, surgical gloves or other items, are to be packaged for sterile preservation.

The film 11 is folded, according to a per se known method, so as to assume, in transverse cross-section, a U-like shape in which both longitudinal flaps 13 and 14 are folded so as to cooperate with a strip 15, so as to form a longitudinal band 16 along the entire package 10.

The strip 15 comprises a tape 17 made of medical-grade paper which is coupled, at the sides, to a corresponding band 18 that has the same dimensions, is made of plastics, and has uniformly distributed fine perforations 19.

Coupling between the tape 17 made of medical paper and the band 18 made of plastics occurs by means of lateral thermal bonds 20 along the entire extension of the strip 15, which is therefore tubular.

The strip 15 is obtained by means of a continuous process, using per se known heat-sealing machines, equipment and methods, and is provided in roll form.

Typically, the film 11 is commercially available wound in rolls which, once installed in equipment of a conventional type, are unrolled, the film 11 being folded according to an automated procedure for continuously manufacturing flexible packages.

The package 10 according to the invention has two longitudinal flaps 13 and 14 of the film 11 which are heat-sealed at the plastic band 18, provided with the small perforations 19, of the strip 15 so as to form corresponding longitudinal heat-sealed regions 20.

The mutually opposite ends 21 and 22 of the package 10 are closed by means of transverse heat-sealed regions in a per se known manner.

The medical-grade paper 17, in particular, is permeable to gases and impermeable to germs, bacteria and the like.

The strip 15 applied longitudinally to the package 10 allows the sterilizing gas to enter and exit through the small perforations 19 of the band 18 and through the medical-grade paper 17, both by spontaneous despressurization and by compression.

Moreover, the strip 15 obtained from the combination of the tape 17 of medical-grade paper coupled to the band 18 made of plastics has mechanical characteristics which make it considerably resistant to tearing and to accidental breakage.

In practice, it is evident that the present invention fully achieves the intended aim and all the above-mentioned objects.

A substantial characteristic is that the packages 10, according to the invention, can be manufactured continuously, since the strip 15 can be obtained separately

and is thus ready to be heat-sealed, according to a per se known method, to each one of said packages 10.

In this manner, the production of the strip 15 does not slow down the production process in any way.

In particular, an important advantage is achieved with the present invention in that an improved sterilizable pouch package is provided having mechanical characteristics such as to ensure that it has an adequate resistance to accidental breakage, especially during the production process.

Another advantage is achieved with the present invention as to the fact that a flexible sterilizable pouch package is provided which can be obtained in practice at a very low and competitive cost with respect to currently commercially available packages.

Another important advantage is ensured by the present invention in that an improved sterilizable pouch package is provided which uses no lacquer, particularly no lacquers based on noxious substances.

Another important advantage is achieved with the present invention as to the fact that a sterilizable pouch package is provided which can be provided in practice by using conventional available equipment and systems, while ensuring a satisfactory production yield.

The present invention is susceptible of numerous modifications and variations, all of which are within the scope of the same inventive concept.

All the details may also be replaced in practice with technically equivalent elements.

The materials employed, as well as the dimensions, may be any according to requirements.

Where technical features mentioned in any claim are followed by reference signs, those reference signs have been included for the sole purpose of increasing the intelligibility of the claims and accordingly such reference signs do not have any limiting effect on the interpretation of each element identified by way of example by such reference signs.

Claims

1. A sterilizable pouch package made of a heat-sealable plastic film, characterized in that at least one portion thereof is permeable to gases and impermeable to germs, bacteria or the like, said portion being a multi layer element obtained by means of at least one medical-grade paper and a backing film.
2. A sterilizable pouch package according to claim 1, characterized in that said portion is shaped like a strip and is bonded between the longitudinal flaps of said heat-sealable plastic film, said strip constituting a part of a wall of said package.
3. A sterilizable pouch package according to claim 2, characterized in that said strip is a thermally-bonded multilayer element composed of a tape of medical-grade paper and of a tape, having similar

dimensions, made of a backing material which is compatible with thermal bonding to said film of heat-sealable plastics that constitutes said package.

4. A sterilizable pouch package according to claim 3, characterized in that said tape made of backing material is a tape made of heat-sealable plastics provided with perforations.

5. A sterilizable pouch package according to claim 4, characterized in that said strip is obtained by means of longitudinal regions in which the flaps of said tape made of medical-grade paper are thermally bonded to said heat-sealable plastic tape provided with perforations, so as to form a tubular element.

6. A sterilizable pouch package according to claim 5, characterized in that said tubular strip is thermally bonded to the longitudinal flaps of said package at the longitudinal flaps of the tape made of heat-sealable plastics provided with said perforations, said tape made of medical-grade paper that composes said strip being arranged outside said package.

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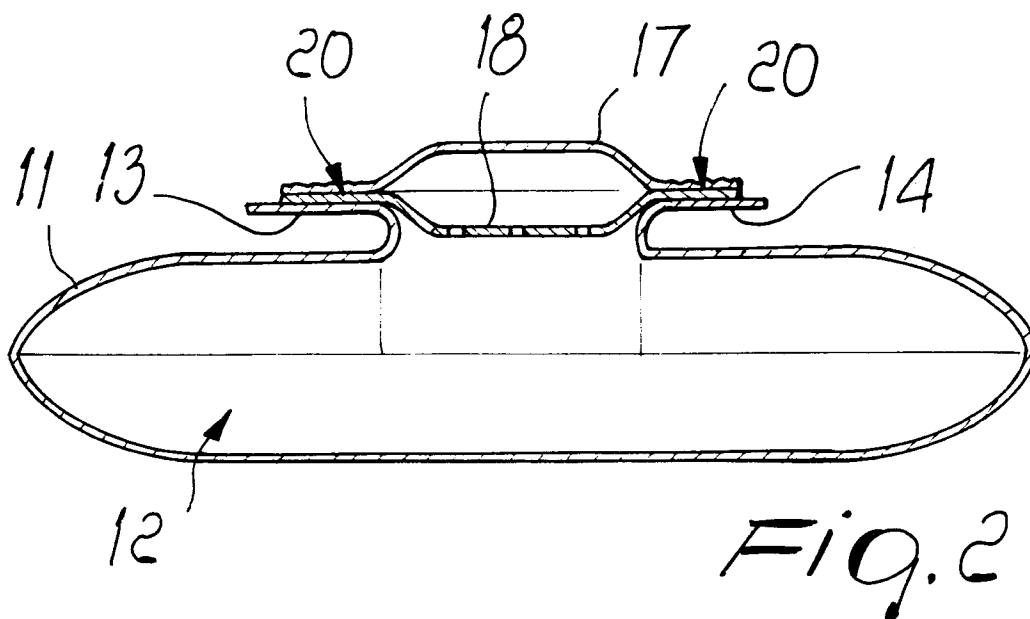
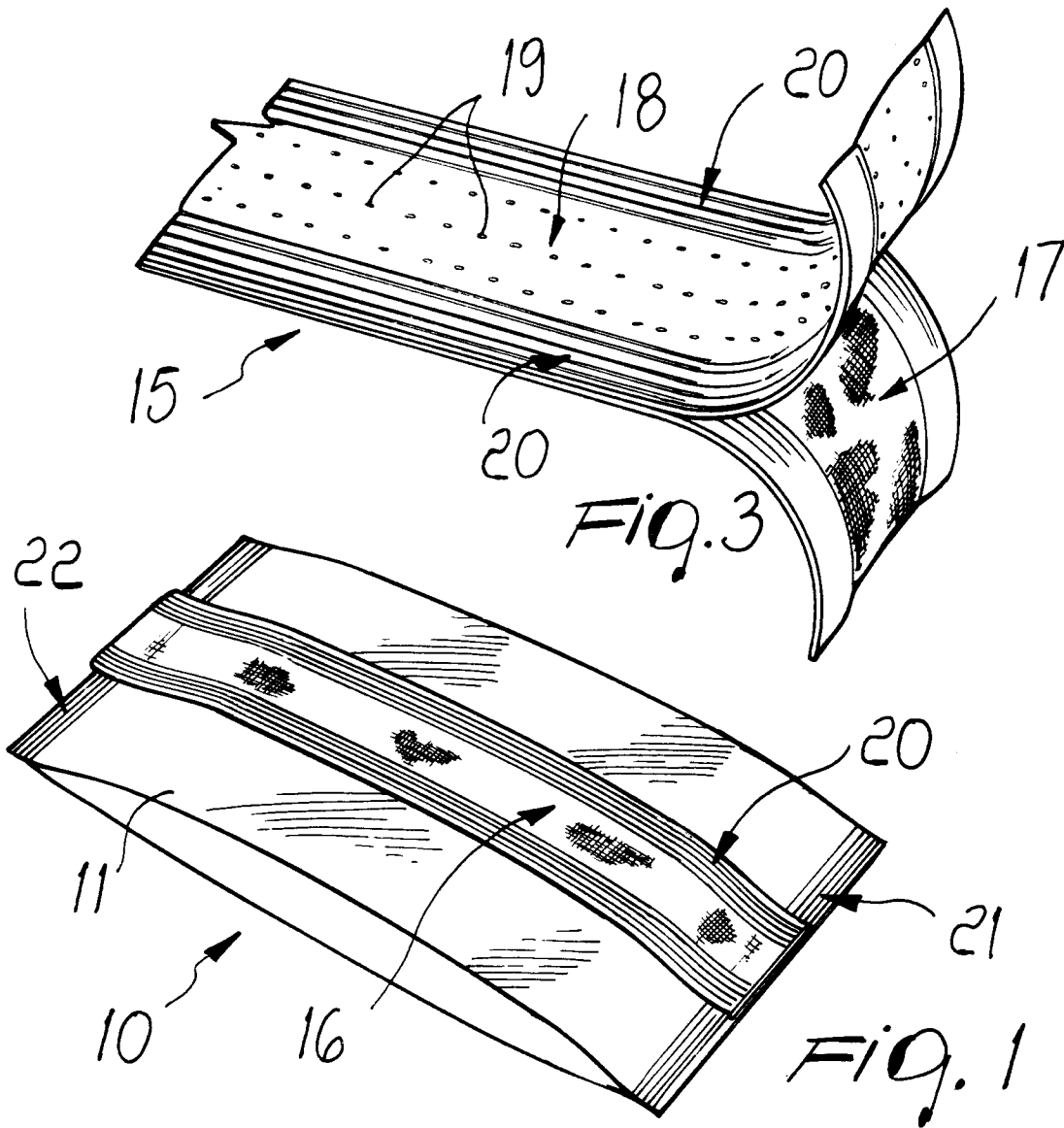
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EUROPEAN SEARCH REPORT

Application Number
EP 98 10 1703

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
X A	US 4 884 694 A (SENGEWALD) * column 5, line 15 - line 43; figure 1A * ---	1 3-6	B65D33/01
A	GB 1 488 326 A (SCHUSTER) * page 3, line 8 - line 120, figure 2 * ---	1,2	
A	US 2 997 224 A (STANNARD) * column 1, line 69 - column 2, line 31; figure 3 * -----	1,2	
			TECHNICAL FIELDS SEARCHED (Int.Cl.6)
			B65D A61L A61M
The present search report has been drawn up for all claims			
Place of search THE HAGUE		Date of completion of the search 12 May 1998	Examiner Bridault, A
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