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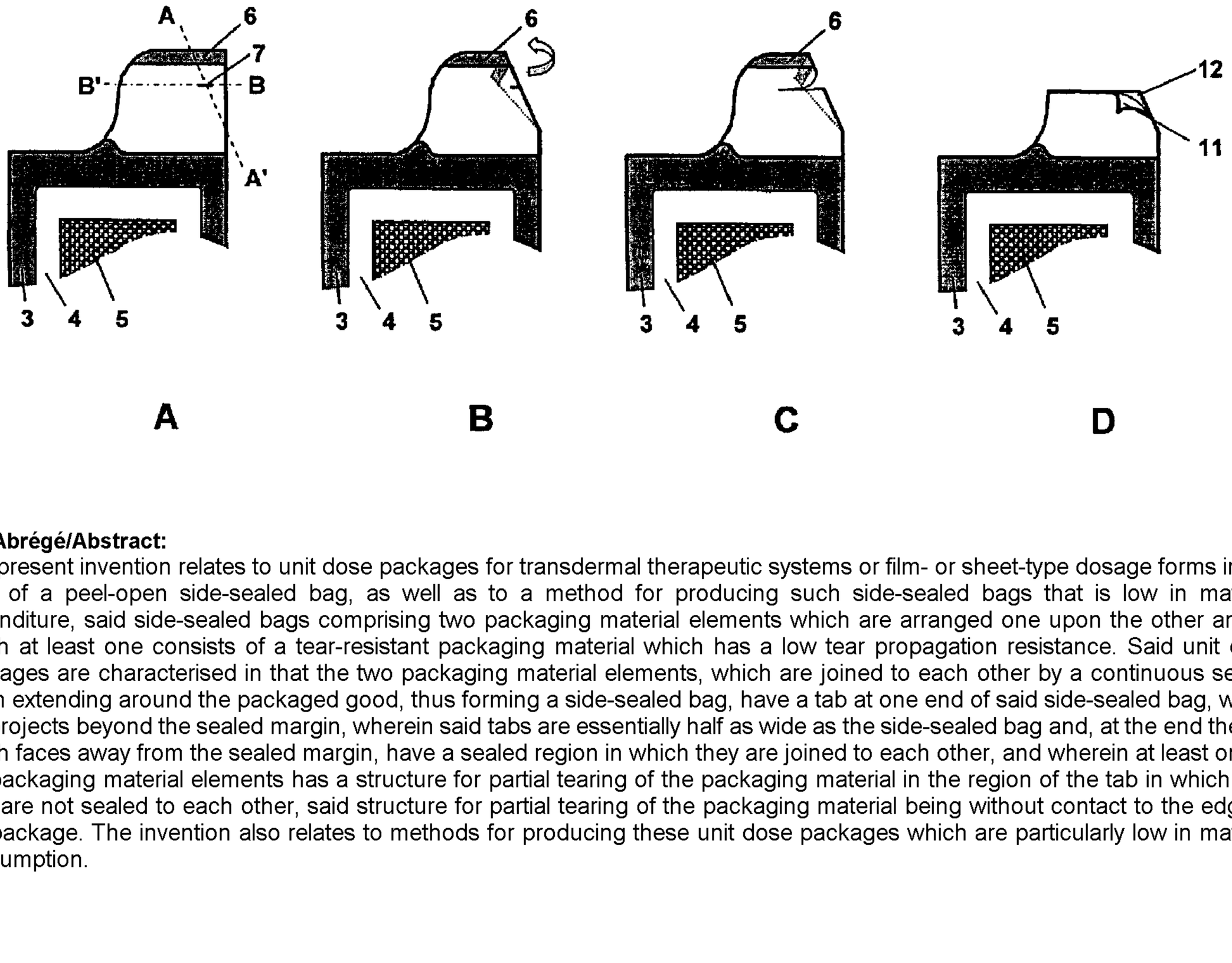
(54) **Titre : EMBALLAGE DE DOSE INDIVIDUELLE AVEC SECURITE ENFANT POUR DES SYSTEMES THERAPEUTIQUES TRANSDERMIQUES OU DES FORMES GALENIQUES PELLICULAIRES**

(54) **Title: CHILDPROOF INDIVIDUAL DOSE PACKAGING FOR TRANSDERMAL THERAPEUTIC SYSTEMS OR FILM-LIKE FORMS OF ADMINISTRATION**



(57) **Abrégé/Abstract:**
The present invention relates to unit dose packages for transdermal therapeutic systems or film- or sheet-type dosage forms in the form of a peel-open side-sealed bag, as well as to a method for producing such side-sealed bags that is low in material expenditure, said side-sealed bags comprising two packaging material elements which are arranged one upon the other and of which at least one consists of a tear-resistant packaging material which has a low tear propagation resistance. Said unit dose packages are characterised in that the two packaging material elements, which are joined to each other by a continuous sealed seam extending around the packaged good, thus forming a side-sealed bag, have a tab at one end of said side-sealed bag, which tab projects beyond the sealed margin, wherein said tabs are essentially half as wide as the side-sealed bag and, at the end thereof which faces away from the sealed margin, have a sealed region in which they are joined to each other, and wherein at least one of the packaging material elements has a structure for partial tearing of the packaging material in the region of the tab in which said tabs are not sealed to each other, said structure for partial tearing of the packaging material being without contact to the edge of the package. The invention also relates to methods for producing these unit dose packages which are particularly low in material consumption.

ABSTRACT

The present invention relates to unit dose packages for transdermal therapeutic systems or film- or sheet-type dosage forms in the form of a peel-open side-sealed bag, as well as to a method for producing such side-sealed bags that is low in material expenditure, said side-sealed bags comprising two packaging material elements which are arranged one upon the other and of which at least one consists of a tear-resistant packaging material which has a low tear propagation resistance. Said unit dose packages are characterised in that the two packaging material elements, which are joined to each other by a continuous sealed seam extending around the packaged good, thus forming a side-sealed bag, have a tab at one end of said side-sealed bag, which tab projects beyond the sealed margin, wherein said tabs are essentially half as wide as the side-sealed bag and, at the end thereof which faces away from the sealed margin, have a sealed region in which they are joined to each other, and wherein at least one of the packaging material elements has a structure for partial tearing of the packaging material in the region of the tab in which said tabs are not sealed to each other, said structure for partial tearing of the packaging material being without contact to the edge of the package. The invention also relates to methods for producing these unit dose packages which are particularly low in material consumption.

Childproof Individual Dose Packaging for Transdermal Therapeutic Systems or Film-Like Forms of Administration

The instant invention relates to unit dose packages for transdermal therapeutic systems or for film-type or sheet-type dosage forms which can be opened easily but are nevertheless child-resistant.

The instant invention further comprises a method for producing the unit dose packages according to the instant invention, said method being characterized by economical use of material.

Medicaments should be packaged partitioned off as single doses to ensure that at a desired point in time only one predetermined dose of the medicinal agent to be administered is taken and to be able to prevent unintentional multiple dosing. In addition, medicaments should be protected from detrimental environmental influences during the storage following their production, to maintain the quality of the medicaments. Containers that contain a plurality of medicament units do not meet these requirements since, because of the container being opened repeatedly to take out the medicament intended for the respective administration, it may happen that inadvertently too many medicament units are taken out of the package. Furthermore, the overall storage stability of the contents of these containers is reduced by the mechanical and/or chemical stress on the medicament units, for example due to moisture or oxygen, accompanying each opening of the container. The higher the sensitivity with which the medicament or the medicinal agent responds to the mechanical and/or chemical stress, the greater the adverse effect on stability.

Another essential aspect in the packaging of medicaments is the safety with regard to protecting individuals from unintended self-medication. Because of their natural curiosity, children, in particular, see packages as a challenge to open them, so that they may unintentionally expose substances that pose a danger to them. For this reason, medicament packages should be configured such that they cannot be opened unintentionally, especially not by children.

On the other hand, packages, including, in particular, packages of medicaments, should be easy to open, so that elderly people, for example, are able to have access to their medicaments without difficulty. A child-proof but elderly-friendly, i.e. easy-to-open, package poses problems to the packaging engineer which appear to be mutually exclusive.

Proposals are known from the prior art for providing easy-to-open, but child-resistant packagings.

The published application EP 1 626 010 A1 discloses a flexible package made of a flexible film which is wrapped around a product and is sealed in the overlap at a longitudinal side as well as at the opposing ends, so that a cavity for the product is formed. The flexible film is essentially tear-resistant; each packaging, however, has a well-located, locally defined weakening area allowing the flexible film to be partially torn by hand and the package to be opened.

The published application US 2006/0138016 A1 relates to a tamper resistant package wherein a packaging material web is provided with at least one recess which serves to receive the item to be packaged, and with a superposed sealing web which are sealed at the margin of the recess, and wherein the sealing web has a strength that prevents the packaged item to be pushed through it on exerting pressure on the packaging material web from outside. Each individual package has two parallel lines of weakness by means of which a corner of the package can be folded inwardly such that the sealing web can be perforated with the pointed corner of the package so as to be able to remove the packaged item.

Solutions to the individual, above-addressed problems are described in the prior art. Thus, the published application DE 10 2004 047 445 A1 discloses a non-reclosable package for products that are hazardous to health, which has
two packaging material elements situated one upon the other; a first surface section on whose edge or edges the two packaging material elements are detachably joined to one another; at least one cavity, which is closed on all sides and is formed between the two packaging material elements while serving to accommodate the packaged good;
and a second surface section that is located outside of said first surface section or is adjoined thereto and on the edge or edges of which the two packaging material elements are detachably joined to one another. At least one of the two packaging material elements is provided with at least one structure which extends inside the second surface section and which enables the packaging material element(s) to be torn.

The published application US 2006/0023976 A1 describes peelable pouches for containing one or more doses of a medicament, wherein two packaging material webs are sealed to each other at the margins thereof, and which in the area of the sealed margin is provided with a tear-

promoting surface structure that is intersected by a fold-over line. The margin of the bag has to be folded along the fold-over line to permit tearing thereof at said surface structure and thus opening the bag.

DE 10 2006 041 921 A1 describes a package for films which contain active substances, which packaging comprises a carrier layer and a covering layer connected releasably to the latter, and has two surface regions in a paired arrangement which lie opposite one another, are separated from one another by a web and within which the covering layer is not connected to the carrier layer, as a result of which two spaces which are separate from one another and are enclosed on all sides are formed for receiving said films in pairs. There is a further surface region within said web, in which further surface region the carrier layer is not connected to the covering layer, as a result of which a hollow space which is enclosed on all sides is formed. There is at least one perforation line within the web.

In the film packagings known from DE 10 2004 047 445 A1, US 2006/0023976 A1 and DE 10 2006 041 921 A1 the task of providing a child-resistant package which at the same time protects the packaged goods from detrimental chemical influences is solved by using a peelable bag made of two films each of which contains a thin aluminium layer, the bag being produced by heat-sealing. These film packages comprise a laterally applied cut which does, however, not cut through the side of the bag itself. As a consequence, the bags have to be folded in the centre of the cut at an angle exceeding 90°, to produce a tear notch in the side of the bag's edge. This exposes an opening aid for gripping, by means of which the two films of the bag can be peeled away from each other.

The packaging of film-type or sheet-type medicaments/dosage forms is a particular challenge as films and sheets are sensitive to chemical (moisture, oxygen) and mechanical stress. To produce packagings having the required protective effect, so-called "high-barrier films/foils", which have a high mechanical load capacity and only permit a low permeation of gases and moisture, if any, have to be utilised as the packaging material. A disadvantage of these films is that they are expensive. In addition, the surface area of film-type or sheet-type pharmaceutical forms is quite large, compared to other pharmaceutical forms for oral application (tablets, coated tablets, capsules, lozenges and the like). The packages required for film-type or sheet-type dosage forms are bigger, related to surface area, than the dosage form itself; in addition it has to be taken into account that the packaging material film must cover both the top side and the bottom

side of the film-type or sheet-type dosage form. As a consequence, in terms of surface area, the amount of packaging material which has to be used is more than double the material of the packaged products. A disadvantageous ratio of packaging costs to product costs is hardly avoidable for individually packaged film-type or sheet-type dosage forms, with the consequence that the costs for the final product are higher than desired.

Although the packaging of individual film-type or sheet-type dosage forms meets the demands in terms of the protection provided to the medicament, it does have the disadvantage that it is very expensive to realise in practice since the required material expenditure is high and the corresponding packages can be produced only comparatively slowly. With the paired approach disclosed in DE 10 2006 041 921 A1, the production costs can be reduced due to a reduction in the machine running time and material expenditure, it is true, but the disadvantage of this approach is that a child-resistant package is possible only where paired films (film-type dosage forms) are packed. Opening the child-resistant closure to expose one dosage form will leave the other dosage form still packaged in a chemically impervious manner, but the package will no longer be child-resistant. For this reason, use of a package according to DE 10 2006 041 921 A1 is appropriate only if the interval between taking the first single dose and taking the second single dose is not too long.

The object of the present invention was to provide an easy-to-open, but child-resistant package for single doses that are present in the form of film-type or sheet-type dosage forms, and for transdermal therapeutic systems (TTSs), which package, compared to the known packages, can be handled more easily and more safely and can be produced at lower cost and/or using less material.

This object is solved by a non-reclosable package in the form of a peel-open side-sealed bag, which bag has an asymmetrically arranged gripping and peel-open aid and is manufactured using a sealable, tear-resistant packaging material that has a low tear propagation resistance. The gripping aid functions as a child safety device, that is, as a safeguard against unintentional opening of the package, and is configured such that the packages can be manufactured in a row, one package following and adjoining the other, thus saving raw-material.

The gripping and tear-open aid of the inventive side-sealed bags forms a surface-complementary tab when paired. This means that the tabs of two congruent side-sealed bags

can be complemented in a surface-complementary manner and placed alongside each other to form a quadrangular surface region, that is, a rectangular or square surface region. This can be achieved by arranging the tab asymmetrically and eccentrically on the side-sealed bag.

The packaging material for producing the side-sealed bags is preferably a packaging material that has low permeation rates for gases and moisture.

Packaging materials having a multilayered structure are particularly suitable for providing the various functions to be fulfilled by the packaging material. In these packaging materials, in which the individual layers are combined to form a composite, preferably in the form of a laminate, the individual layers of the packaging material fulfil one or more functions. However, for the packages according to the invention monolayered films/sheets or foils, too, may be used as the packaging material, providing these films/sheets or foils are, at least, capable of fulfilling all of the necessary functions of the packaging material.

The side-sealed bag consists of two packaging material elements, a first packaging material element and a second packaging material element, lying on top of each other; between which there is located the packaged good, for example the transdermal therapeutic system or the film-type or sheet-type dosage form. The packaged good is enclosed by a circumferential and continuous, i.e. uninterrupted sealed seam between the two packaging material elements.

The packaging material for the packaging material elements of the side-sealed bags according to the invention is tear resistant while at the same time having a low tear propagation resistance. Because of the tear resistance of the package, it is not possible to tear the package open by hand, i.e. without using auxiliary means such as scissors, knives or teeth.

However, an existing tear can be extended and a propagation of the tear be achieved at a predetermined, weakened location, for example at a notch, so that further tearing by hand will be possible without auxiliary means.

The tear resistance of the packaging material is at least 20 N, preferably at least 50 N and more preferably at least 70 N. Preferably, the tear resistance of the packaging material is below 2000 N, more preferably below 150 N and still more preferably below 100 N, measured at the interconnected packaging material elements which form the package.

The tear propagation resistance of the packaging material must not be too low because this would mean that sufficient protection of the packaged goods can no longer be guaranteed and that there is a risk of the above-mentioned gripping aids being torn off on opening the package. This can be determined by means of simple experiments. The tear propagation resistance of the packaging material is less than 10 N, preferably less than 2 N, more preferably less than 1.5 N, and preferably more than 0.5 N, measured at the two interconnected packaging material elements which form the package.

The tear resistance and the tear propagation resistance of the packaging material can be determined by means of known tensile testing machines using a sample holder for tear-resistance tests (type No. 00740) (available, for example, from FRANK Prüfgeräte GmbH, D-69488 Birkenau).

To permit or facilitate tear propagation in the packaging material, the tear resistance is a multiple of the tear propagation resistance. The ratio of tear resistance to tear propagation resistance is preferably in the range from 2:1 to 200:1, more preferably in the range from 50:1 to 150:1, relative to the tear resistance and tear propagation resistance of the two interconnected packaging material elements.

Packaging materials having the above-mentioned properties (tear resistance, tear propagation resistance) are known to the person skilled in the art; they are preferably film- or foil-type, flexible materials made of plastic, metal (e.g. aluminium), or composite materials of the aforementioned materials. Particularly suitable packaging materials are polyester films. As film- or foil-type materials, both monofilms or -foils and two-layer or multilayer laminates may be utilised. Suitable for use as the plastic materials are in particular the following materials, singly or in combination: polyester (e.g. polyethylene terephthalate), polyethylene (e.g. HDPE, LDPE), polypropylene, polyisobutylene, polystyrene, polyvinylchloride, polyamide, polycarbonate, cellulose acetate. The thickness of the film- or foil-type materials is preferably in the range from 5 to 300 µm, more preferably 50 to 200 µm.

A further, preferred film material is Barex® (BP Chemicals) – a copolymer of acrylonitrile and butadiene. Because of its good barrier properties and chemical resistance it is especially suit-

able for packaging medicaments having a content of aggressive and/or volatile active agents, e.g. nicotine.

The packaging material for the package according to the invention must be sealable to enable the two packaging material elements to be welded to one another, preferably by heat sealing, but also by any other suitable heat sealing method or cold sealing method, such as ultrasound sealing, laser sealing, or comparable film welding methods known to those skilled in the art.

Suitable sealable materials must be chemically impervious to moisture and air in order to ensure that the product is protected from external environmental factors. At the same time it is necessary that, after the sealing, these materials allow the connection of the two packaging material elements to be undone by applying a low tear-open force for opening the package.

In a preferred embodiment, the packaging material has a sealable layer that faces the product. Such sealable layers are based on polyethylene and are commercially available. Examples are the Core-Peel™ technology soled by the company Amcor Flexibles, and comparable polyethylene-based materials soled by many manufacturers of packaging material, such as the companies Danapak, Huhtamaki, Alcan or Klöckner.

The above-mentioned detachable connections are preferably formed by sealed seams or sealed areas, for which peelable film lacquers (peel lacquers) or hot-melt adhesives may be utilised as the sealing medium. Suitable sealing compounds and sealing methods are known to those skilled in the art, e.g. sealing compounds based on LD polyethylene or ethylene-vinyl acetate copolymers.

The sealed seams or sealed areas preferably have a width from 0.1 mm to 10 cm, more preferably a width from 1 mm to 2 cm, and still more preferably a width of 2 mm to 8 mm, and they preferably extend over the entire length or width of the packaging material elements. At particularly exposed locations, the width of the sealed seam may also be greater. To additionally impede opening of the package, at least one of the sealed seams may have greater width than the other sealed seams.

The tear-open force for peeling open easily separable sealings is in the range from 1-50 N/15 mm sealed seam width, preferably in the range from 3-20 N/15 mm. This means that the sealed

seams or sealed areas preferably have a strength (= seal strength) in the range from 1 N/15 mm to 50 N/15 mm, preferably 2 N/15 mm to 20 N/15 mm.

In one preferred embodiment the packaging material is impermeable or scarcely impermeable to gases and moisture, that is, it has low permeation rates for gases and moisture. Preferably, the packaging material comprises a high-barrier layer in the form of an aluminium-containing film. However, the packaging material may also comprise any other high-barrier film. Films made of polychlorofluoroethylene (PCTFE), commercially available from the company Honeywell under the trade name Aclar™, films made of cyclic olefin copolymers (COC), soled under the trademark Topas® by the company Ticona, and polyethylene terephthalate films with a ceramic SiO_x or AlO_x coating are mentioned here by way of example.

The two packaging material elements may be made from the same or different materials. Preferably at least one of the two packaging material elements consists of transparent materials (e.g. transparent plastic film).

The invention furthermore comprises embodiments wherein one packaging material element or both packaging material elements have the same colouring; each of these colourings may be a transparent or an opaque colouring. For example, one of the two packaging material elements may be made from a composite material of paper (or paperboard) with plastics (e.g., polyethylene-coated or polyethylene terephthalate-coated paper), and the second packaging material element may be made from a transparent, colourless or coloured plastic film. To reduce the permeability to air, light and water vapour, it is advantageous if at least one surface of the carrier layer or/and the cover layer is metal-coated (e.g. coated with aluminium).
In one specific embodiment, at least one of the packaging material elements of the side-sealed bag is a packaging material that contains an oriented material, that is, a monoaxially stretched material. When using a monoaxially stretched material, the low tear resistance is directed transversely to the gripping tab. Separating the child-safety device can thereby be facilitated if the direction of tearing for separating the child-safety device lies in the direction of the weaker tear propagation resistance.

An example of a particularly preferred packaging material is a composite of monoaxially stretched polypropylene (50 µm – 70 µm thick), aluminium (9 µm – 20 µm thick) and polyethylene (20 µm – 100 µm thick).

The distinctive feature of the side-sealed bags according to the present invention consists in the configuration of a tab on each of the two packaging material elements, which tab serves as a gripping aid and permits the two packaging material elements to be seized separately and without which opening the package cannot be successful because the tear resistance of the packaging material prevents this.

This gripping aid is a surface-complementary tab. This means that the tabs of two congruent side-sealed bags can be complemented in a surface-complementary manner and placed alongside each other to form a quadrangular surface region.

The package according to the invention will in the following be explained with reference to the figures. Said figures only serve to illustrate the invention but do not in any way limit the invention to what is represented therein.

Figure 1 shows a preferred embodiment of the inventive unit dose package in plan view.

Figure 2A shows the front edge of a preferred embodiment of the unit dose package according to the invention, prior to opening.

Figure 2B shows the region of the unit dose package according to Figure 2A, with the upper right-hand corner of the tab having been folded over along the line A-A' shown in Figure 2A, such that the structure for partial tearing of the packaging material allows the packaging material to be further torn along the line B-B'.

Figure 2C shows the region of the unit dose package according to Figure 2A, with the tab having been partially torn at the structure permitting partial tearing of the packaging material, along the line B-B' shown in Figure 2A.

Figure 2D shows the region of the unit dose package according to Figure 2A after the child-safety device has been torn off, so that the two tabs of the packaging material elements, which serve as a gripping aid, are exposed.

Figure 3A illustrates the separating forces which are required for opening a package known from the prior art, said package being provided with a gripping aid running across the entire width of the side-sealed bag.

Figure 3B illustrates the separating forces necessary for opening the package known from the prior art, wherein the sealed seam that is directed towards the gripping aid is configured in V-shape.

Figure 3C illustrates the separating forces necessary for opening a package according to the present invention that has an asymmetric gripping aid extending across half the width of the side-sealed bag.

Figure 4 is a draft of the arrangement of unit dose packages according to the invention during serial production thereof from web material.

Figures 5A to 5D illustrate various embodiments of surface-complementary tabs.

Figure 6 shows a pair of packages illustrating the point-symmetric principle observed in the pairwise arrangement of two unit dose packages.

The packaging (1) according to the invention is a side-sealed bag made of two packaging material elements (11, 12), arranged so as to lie on top of each other, one packaging material element of which forming the cover layer and the other packaging element forming the support, between which is arranged the packaged product (5), preferably a transdermal therapeutic system or a film-type or sheet-type dosage form. The two packaging material elements are sealed to each other in such a way that the packaged article (5) is surrounded by a circumferential, continuous sealed margin (3). This way, a compartment (4) closed on all sides is formed which contains the packed article.

The side-sealed bag (1) has a front edge (8), a rear edge (9) and two, preferably parallel, lateral edges (10, 10').

Each one of the two packaging material elements (11, 12), which are arranged one upon the other and are interconnected by means of the sealed margin (3), has a marginal tab (2) which,

on that side of the sealed margin which will be referred to in the following as the front end, projects asymmetrically beyond the sealed margin (3) that is located at said front end.

The tabs (2) of the two packaging material elements are substantially half as wide as the side-sealed bag. The front edge (8) of the inventive unit dose package, which on the one half thereof is formed by the front sealed margin (3) and on the other half thereof is formed by the tabs (2), may extend in the shape of an S, or sigmoidally, angularly, obliquely or diagonally.

The tabs are configured so as to be surface-complementary, with the result that two tabs of congruent side-sealed bags can be complemented and positioned alongside each other by pairing so as to form a quadrangular surface region.

The superposed tabs of the two packaging material elements are, at the end thereof which faces away from the sealed margin (3), sealed to each other in a small strip that extends over the entire width of the tabs in that region. This sealed region (6) constitutes an essential component of the child-resistant device of the packaging according to the invention.

The child-resistant quality of the packaging is achieved by virtue of the fact that the tabs, functioning as gripping aids necessary for tearing the package open, can be exposed only by overcoming a child safety device. This safety device consists in that the two regions of the packaging material elements which form the tab, on account of their being sealed in the sealing region (6), cannot be easily separated from one another. Because of the tear resistance of the packaging material, it is not possible to tear off the child-resistant device, that is, to remove the sealed region (6), by hand.

Exposure of the gripping aids is effected by tearing off the rear sealing (6) after folding the tabs along line A-A', said line A-A' extending through a structure (7) for partial tearing of the packaging material in at least one of the two packaging material elements in the region of the tabs where the two packaging material elements are not sealed to each other. Here, the low tear propagation resistance comes to bear without which the sealing (6) cannot be torn away.

The structure (7) for partial tearing of the packaging material is arranged in the region of the tab where the two tabs are not sealed to each other. The structure for partial tearing of the packag-

ing material is not in contact with the margin, and is not in contact with the edge of the packaging material elements.

The structure for partial tearing of the packaging material enables a person to overcome the initial tear resistance when the structure comes into marginal contact with the outline of the packaging. Only then is it possible, by virtue of the relatively low tear propagation resistance of the packaging material, to tear the packaging material along the line B-B' without the use of tools, in order to tear off the sealing region (6) serving as a child-safety device.

The structure for partial tearing of the packaging material can be formed directionally by incision, but also by local weakening, e.g. by exposure to irradiation such as described in EP 1 626 010 A1. The structure for partial tearing is provided in the region of the tabs where the two packaging material elements are not welded to each other, preferably at a position nearer to the sealed region (6) than to the sealed margin (3), so that after tearing away the sealed margin (6) the size of the gripping aids is still sufficient.

Through this arrangement of the structure for partial tearing of the packaging material, i.e. neither in the area of the sealed margin nor within the side-sealed bag, the proofness of the packaging is not interfered with.

According to the invention, the structure for partial tearing should not be in marginal contact with the packaging, so that only when folding the tab along a line which runs through said structure, for example along line A-A' (Fig. 2A), will the structure cut the margin of the outline, which outline has been formed by effecting the folding (FIG. 2B).

Preferred structures which are suitable as the structures enabling the partial tearing of the packaging material element(s) are: straight cuts, jagged cuts, undulating cuts, perforations, especially perforations of successively arranged points and/or cuts, material recesses, punchings, especially arrow-type, triangular or diamond-shaped punchings, and predetermined breaking points.

Said structure enabling the partial tearing of the packaging material element(s) may be present in one of the two packaging material elements or in both packaging material elements, with the last-mentioned embodiment being preferred. In this latter case, the structures for partial tearing

of the packaging material are preferably configured in both packaging material elements such that they are alike or similar, and are preferably arranged so as to be congruent with each other.

Due to the high tear resistance and avoidance of inwardly extending notches in the circumference, normal use does not permit initial partial tearing. By folding at the weakened point of the longitudinal axis, it is possible to achieve partial tearing and to separate the welded area of the gripping aid. The gripping aid of both packaging material elements can thereby be seized and tearing can be performed via a corner. By tearing open via a corner, the need for very high peel force maxima, compared to the average peel force, is avoided.

Opening of the package generally takes place in such a manner that the two packaging material elements are folded over along a line that runs through the structure for partially tearing the packaging material (FIG. 2A), so that said structure touches the border of the packaging outline, which outline has been formed by effecting the folding (Fig. 2B). On account of the low tear propagation resistance, the child-resistant device (6) can then initially be partially torn (FIG. 2C) and subsequently torn off. As a consequence, the tabs of the two packaging material elements become separately accessible (FIG. 2D) and will now serve as gripping aids for tearing open the sealed margin between the two packaging material elements, thus making the packaged product accessible.

Through the inventive combination of packaging material and design of the child-safety device, it is possible to configure the packaging such that opening thereof will only be possible by an ordered sequence of four steps:

(i) folding or folding over of the package along a line, the weakening structure thereby becoming accessible for partial tearing;

(ii) partial tearing of the packaging at the weakening structure, which is now located at the margin, and tearing further along said structure,

(iii) seizing the now-exposed tabs of the packaging material elements as gripping aids (tear tabs), and

(iv) pulling apart and undoing the sealed margin between the packaging material elements.

This handling presents considerable difficulties to children, especially small children, but can be performed by adults without any difficulty and without the use of tools. In a particularly preferred

embodiment the unit dose package is child-resistant in accordance with DIN EN 14375 and/or according to ASTM D3475-03a.

The only possibility of opening the package without using tools consists in pulling open the sealing of the two packaging material elements. The presence and sufficient size of the gripping aid constitute a necessary precondition for doing this.

The tabs should be at least 5 mm, preferably at least 10 mm and more preferably at least 15 mm long. The length of the tabs does preferably not exceed 30 mm, and more preferably it does not exceed 25 mm.

The width of the tabs substantially amounts to 0.5 times the overall width of the package, preferably at least 5 mm. In especially preferred embodiments, the width of the tabs is at least 10 mm, and still more preferably at least 15 mm. In especially preferred embodiments, the width of the tabs does not exceed 50 mm, and in even more preferred embodiments it does not exceed 30 mm.

In a likewise feasible embodiment using high-barrier packaging material (e.g. containing aluminium), a special feature according to the invention consists in that a marking, e.g. a batch number, can be applied on the package in the region of the gripping tab by laser marking or punching. The special technical benefit consists in that the proofness of the package, in the bag itself, cannot be jeopardised by marking with a laser or by punching, even if, due to product tolerances, the laser punctures the barrier layers, or if the aluminium barrier is destroyed by punching.

The eccentric position of the tab enforces the start of the peel-open process via one of the corners (FIG. 3C). As a consequence, during the entire progress (y) of the peel-open process the separating force (X) required for peeling open the side-sealed bag is smaller than in the case of a central positioning of the gripping aids, which would lead to the seal being peeled open under 90°, as in conventional packages according to FIG. 3A.

When peeling open a known package, as shown in FIG. 3A, one first needs to peel open the sealed seam at the front side over its entire width. This requires a considerably higher separat-

ing force than is necessary for peeling open the sealed seam in the region of the sides (FIG. 3A).

By contrast, the location of the gripping aids according to the invention allows the side-sealed bag to be pulled open more easily and thereby more evenly, at least initially.

It is known from the prior art to reduce the separating force required for peeling open side-sealed bags by providing a V-shaped sealed seam (FIG. 3B). Compared to this state of the art, the design according to the invention (FIG. 3C) enables a considerable reduction in the required packaging material while providing the same functionality.

The gripping and tear-open aid of the inventive side-sealed bags is a tab that is surface-complementary when paired. This means that it is possible to complement the tabs of two congruent side-sealed bags and place them alongside each other in a surface-complementary manner, to form a quadrangular surface region (FIG. 5A to 5D, FIG. 6). This can be achieved by arranging the tab asymmetrically and eccentrically on the side-sealed bag.

Figures 5A to 5D show different embodiments of the surface-complementary tabs, which can be produced, for example, by an S-shaped or sigmoid (FIG. 5A and 5B), an angular (FIG. 5C), or an oblique or diagonal (FIG. 5D) cut in the surface section in which the packaging material webs are not sealed to each other.

The present invention also relates to a method of producing a unit dose package for transdermal therapeutic systems or film-shaped dosage forms. This method is characterised in that the consumption of material is particularly low as compared to the known methods. Due to the surface-complementary design of the tabs, the unit dose packages can be made from a web-shaped packaging material without producing any waste packaging material. As a consequence, the unit dose packages according to the invention can be manufactured without loss of packaging material. FIG. 4 illustrates a waste-free manufacture of the unit dose packages from packaging material webs, wherein a plurality of pairs of packages (500), each consisting of two unit dose packages which are linked in the region of their tabs.

In the above case, the two unit dose packages of a pair of packages are linked in point-symmetric manner via their tabs. FIG. 6 visualises this point-symmetric arrangement of two unit

dose packages with the dotted lines C-C' and D-D', whose point of intersection indicates the centre of symmetry.

The method according to the invention comprises the following steps:

- providing a first packaging material web;
- providing a second packaging material web;
- positioning the good to be packaged on one of the two packaging material webs;
- placing the packaging material webs on top of each other and connecting them such that for each good to be packaged a compartment, closed on all sides, for receiving the good to be packaged is formed, and detachably interconnecting the two packaging material elements at the margin or margins of said compartment, with two unit dose packages that succeed each other in the direction of the web being arranged in pairs at a time in such a way that the sealed margins facing each other are directly adjacent to one another, and with a surface section remaining between the two successive unit dose packages of a pair, in which surface section the two packaging material webs are not sealed to each other;
- applying two structures for partial tearing of the packaging material in at least one of the two packaging material webs, said structures being applied at the opposing longitudinal edges within the surface section in which the two packaging material webs are not sealed to each other; and
- separating the successive pairs of packages by making a cut along a line that runs transversely to the web direction of the packaging material webs, and separating the unit dose packages of a pair of packages by partitioning off the two unit dose packages of a pair of packages by making a cut along a line that, in one longitudinal half of the interconnected packaging material webs runs in the region of the front sealed margin of a unit dose package of a pair of packages, and in the other longitudinal half of the interconnected packaging material webs runs in the region of the front sealed margin of the other unit dose package of said pair of packages, so that surface-complementary tabs are formed.

The sequence of method steps indicated above is not compulsive; for example, the structures for partial tearing of the packaging material may be produced already after the first or second of

the above-described steps. The term "cut" encompasses any method of cutting plastic films known to those skilled in the art, including blanking.

The peelable connection between the packaging material elements is preferably produced by heat-sealing at temperatures in the range of between 50 °C and 200 °C, especially 50 °C to 90 °C, using "hotmelts". However, the peelable connection between the two packaging material webs may also be produced by other heat-sealing or cold-sealing methods, such as ultrasound sealing, laser sealing or the like.

The packages according to the invention can be produced with low expenditure of material by choosing a suitable complementary geometry of two adjacent unit dose packages (in the manner of Escher figures). With the design of the tabs according to the present invention, the width of the tabs being essentially half that of the unit dose package, the tabs of two successive unit dose packages can be made from one and the same section of the packaging material web if the one package is arranged in a position rotated by 180° about its vertical axis, i.e. about the axis running transversely to the surface plane of the unit dose package and thus of the packaging material webs. The two unit dose packages arranged in this way around a centre of symmetry form a pair of packages in which the unit dose packages, which adjoin each other with their front edges, can be separated by means of a single cut, without loss, to give two identical single packages that are identical in terms of their surface-area and shape (FIG. 4).
In this way the packaging material is used in an efficient manner since the gripping aid does not need to extend along the entire width of the package but two packages which, in the machine running direction, are proximate share one advance length required for the advance of the gripping aid. The material needed for the gripping aid is thereby halved. The unit dose packages are, however, identical on account of their complementary design. At the same expenditure of material, the possible length of the gripping aid, and thereby the possibility of applying a force when tearing the bag open, can be twice the length of a gripping aid in unit dose packages that have been produced without the complementary, paired arrangement according to the invention.

The package can be efficiently manufactured from web material in serial production, on rotary sealing machines. One sealing, which may be elegantly realised by a set-up, will seal a pair of side-sealed bags (500), with the two single packages (100, 200) forming said pair being linked in the region of the gripping aid, and being separated from each other at a later point in the pro-

duction process. The gripping aid according to the invention may be produced by making a cut along a line running in the shape of an S, or sigmoidally, angularly, obliquely or diagonally through the surface section in which the two packaging material webs are not sealed to each other. Hence, the cut is made within the free space between the two unit dose packages forming the pair in such a way that the weld at the distal end of the gripping aid of one unit dose package of the pair is located in the sealed margin of the other unit dose package of said pair and vice versa. As a consequence the tolerance regarding the location of the cut is, within relatively wide ranges, non-critical to the child-resistant closure (in the instant example, approximately 1-2 mm tolerance of location).

In the serial production from a web material, several of the aforementioned pairs of two unit dose packages succeed each other in such a way that a pair can be separated from the following pair by making a cut which extends transversely to the direction of the web, along line (9).

Claims:

1. A unit dose package, for a packaged good or article that is surrounded by a sealed seam or margin, for transdermal therapeutic systems or for film- or sheet-type dosage forms, in the form of a peel-open side-sealed bag, comprising:

- two packaging material elements, arranged one upon the other, wherein at least one of the two packaging material elements consists of a tear-resistant packaging material having a low tear propagation resistance;

- the two packaging material elements being joined to each other by a continuous sealed seam extending around the packaged good to form the side-sealed bag which defines a compartment for holding the packaged good;

- each of the two packaging material elements having a tab at one end of said side-sealed bag, wherein the tab projects beyond the sealed margin,

- each of said tabs being half as wide as the side-sealed bag;

- wherein, at the end of the side-sealed bag facing away from the sealed margin, the tabs have a sealed region, wherein the tabs are joined to each other and an unsealed region wherein the tabs are not joined to each other;

- at least one of the packaging material elements having a structure for partial tearing of the packaging material in the unsealed region of the tabs, said structure for partial tearing of the packaging material not being in contact with an edge of the package; and,

- wherein each of the tabs is arranged asymmetrically and eccentrically on the side-sealed bag.

2. The unit dose package according to claim 1, wherein the tabs of two congruent side-sealed bags can be complemented and arranged alongside each other in a surface-complementary manner to form a quadrangular surface region.

3. The unit dose package according to claim 1 or 2, wherein the tear resistance of the packaging material is between 20 N and 2000 N, measured at the two interconnected packaging material elements which form the unit dose package.

4. The unit dose package according to claim 1 or 2, wherein the tear resistance of the material is between 50 N and 150 N, measured at the two interconnected packaging material elements which form the unit dose package.

5. The unit dose package according to claim 1 or 2, wherein the tear resistance of the material is between 70 N and 100 N, measured at the two interconnected packaging material elements which form the unit dose package.

6. The unit dose package according to any one of claims 1 to 5, wherein the tear propagation resistance is less than 10 N, measured at the two interconnected packaging material elements which form the unit dose package.

7. The unit dose package according to any one of claims 1 to 5, wherein the tear propagation resistance is less than 2 N, measured at the two interconnected packaging material elements which form the unit dose package.

8. The unit dose package according to any one of claims 1 to 5, wherein the tear propagation resistance is less than 1.5 N, measured at the two interconnected packaging material elements which form the unit dose package.

9. The unit dose package according to any one of claims 1 to 8, wherein the ratio of tear resistance to tear propagation resistance lies in the range of from 2:1 to 200:1, relating to the tear resistance and tear propagation resistance of two interconnected packaging material elements forming the unit dose package.

10. The unit dose package according to any one of claims 1 to 8, wherein the ratio of tear resistance to tear propagation resistance lies in the range of from 50:1 to 150:1, relating to the tear resistance and tear propagation resistance of two interconnected packaging material elements forming the unit dose package.

11. The unit dose package according to any one of claims 1 to 10, wherein the tear-open force for peeling the two interconnected packaging elements open lies in the range from 1-50 N/15 mm of the width of the sealed seam.

12. The unit dose package according to any one of claims 1 to 10, wherein the tear-open force for peeling the two interconnected packaging elements open lies in the range from 3–20 N/15 mm of the width of the sealed seam.

13. The unit dose package according to any one of claims 1 to 12, wherein the structure for partial tearing of the packaging material is selected from the group of structures consisting of straight cuts, jagged cuts, undulating cuts, perforations, especially of successively arranged holes or cuts, material recesses, punchings, especially arrow-like, triangular and diamond-shaped punchings, and predetermined breaking points.

14. The unit dose package according to claim 13, wherein the punchings are arrow-like, triangular or diamond-shaped punchings.

15. The unit dose package according to any one of claims 1 to 14, wherein at least one of the packaging material elements is formed from a monolayer or a multilayer film or sheet.

16. The unit dose package according to any one of claims 1 to 15, wherein the good packaged therein is inaccessible to children without the use of tools.

17. The unit dose package according to any one of claims 1 to 16, wherein the good packaged therein is child-resistant according to DIN EN 14375 and/or to ASTM D3475-03a.

18. A method of producing a unit dose package according to any one of claims 1 to 17, comprising the steps of:

- providing a first packaging material web;
- providing a second packaging material web;
- positioning the good to be packaged on one of the two packaging material webs;
- placing the packaging material webs on top of each other and connecting them such that for each product to be packaged a compartment, closed on all sides, for receiving the good to be packaged is formed, and detachably interconnecting the two packaging material elements at the margin or margins of said compartment, with two unit dose packages that succeed each other in the direction of the web being arranged in pairs at a time in such a way that the sealed

margins facing each other are directly adjacent to one another, and with a surface section remaining between the two successive unit dose packages of a pair, in which surface section the two packaging material webs are not sealed to each other;

- applying two structures for partial tearing of the packaging material in at least one of the two packaging material webs, said structures being applied at the opposing longitudinal edges within the surface section in which the two packaging material webs are not sealed to each other; and

- separating the successive pairs of packages by making a cut along a line that runs transversely to the web direction of the packaging material webs, and separating the unit dose packages of a pair of packages by partitioning off the two unit dose packages of a pair of packages by making a cut along a line that in the one longitudinal half of the interconnected packaging material webs runs in the region of the front sealed margin of a unit dose package of a pair of packages, and in the other longitudinal half of the interconnected packaging material webs runs in the region of the front sealed margin of the other unit dose package of said pair of packages, so that surface-complementary tabs are formed.

19. The method according to claim 18, wherein the cut for separating the two unit dose packages forming a pair of packages extends in the shape of an S, or sigmoidally, angularly, obliquely or diagonally through the surface section in which the two packaging material webs are not sealed to each other.

20. The method according to claim 18 or 19, wherein the packaging material webs are interconnected by sealed seams or sealed areas, especially by using a sealing lacquer.

21. The method according to claim 20, wherein the packaging material webs are interconnected by using a sealing lacquer.

22. The method according to any one of claims 18 to 21, wherein both packaging material webs are provided, in the section thereof where the packaging material webs are not sealed to each other, with at least one structure for partial tearing of the packaging material.

23. The method according to claim 22, wherein at least one structure for partial tearing comprises more than one structure and wherein said structures are alike and arranged so as to be congruent with each other.

24. The method according to any one of claims 18 to 23, wherein the at least one structure for partial tearing of the packaging material are selected from the group of structures which consists of straight cuts, jagged cuts, undulating cuts, perforations, especially of successively arranged holes or cuts, material recesses, punchings, and predetermined breaking points.

25. The method according to claim 24, wherein the punchings are arrow-like, triangular or diamond-shaped punchings.

26. The method according to any one of claims 18 to 25, wherein for each unit dose package a fold-over line or bending line is applied that extends from the front edge of the unit dose package to that longitudinal edge of the unit dose package at the side of which is located the structure for partial tearing of the packaging material, and that intersects said structure.

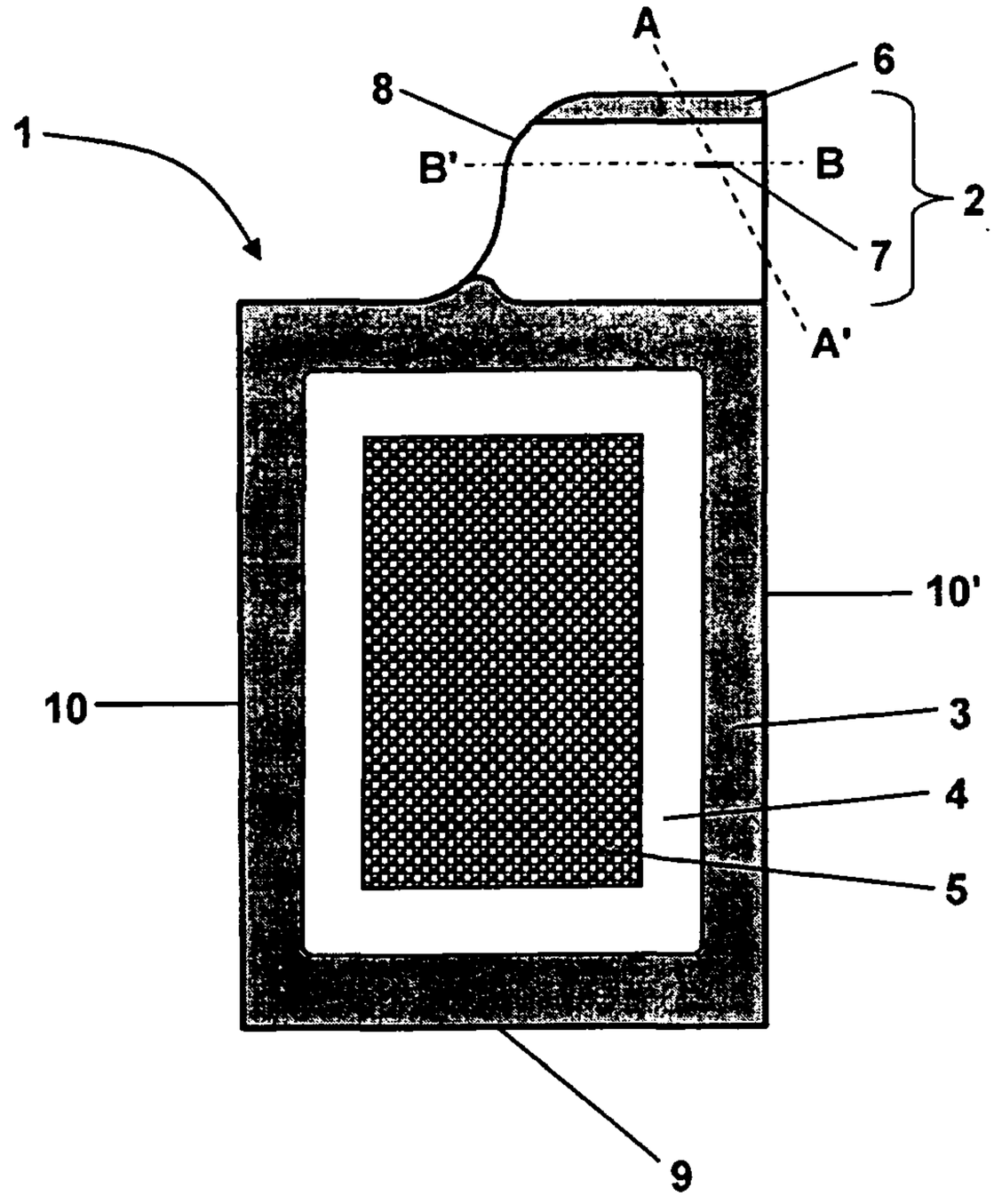


FIG. 1

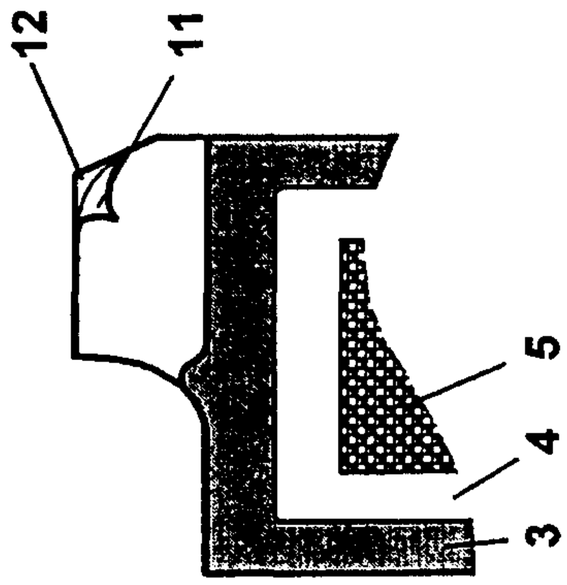


FIG. 2D

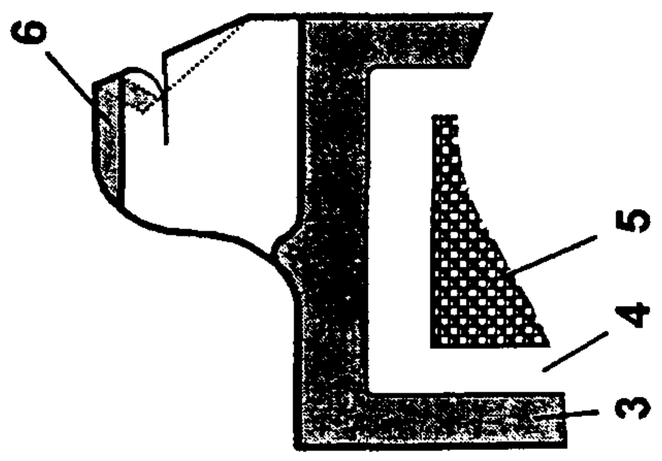


FIG. 2C

FIG. 2B

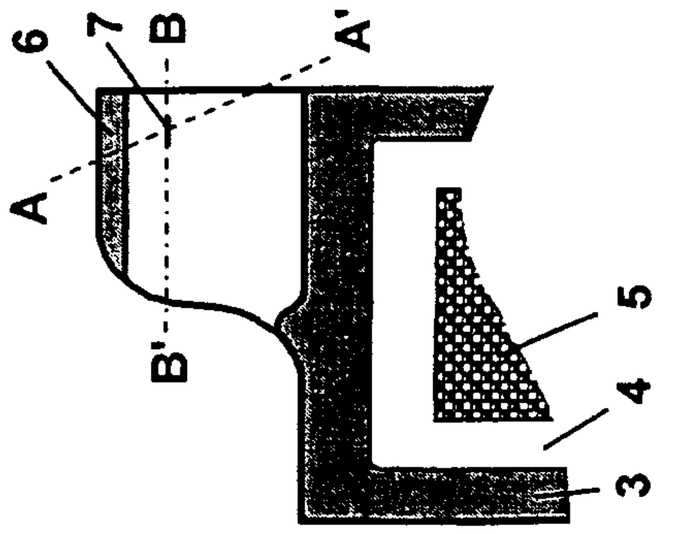


FIG. 2A

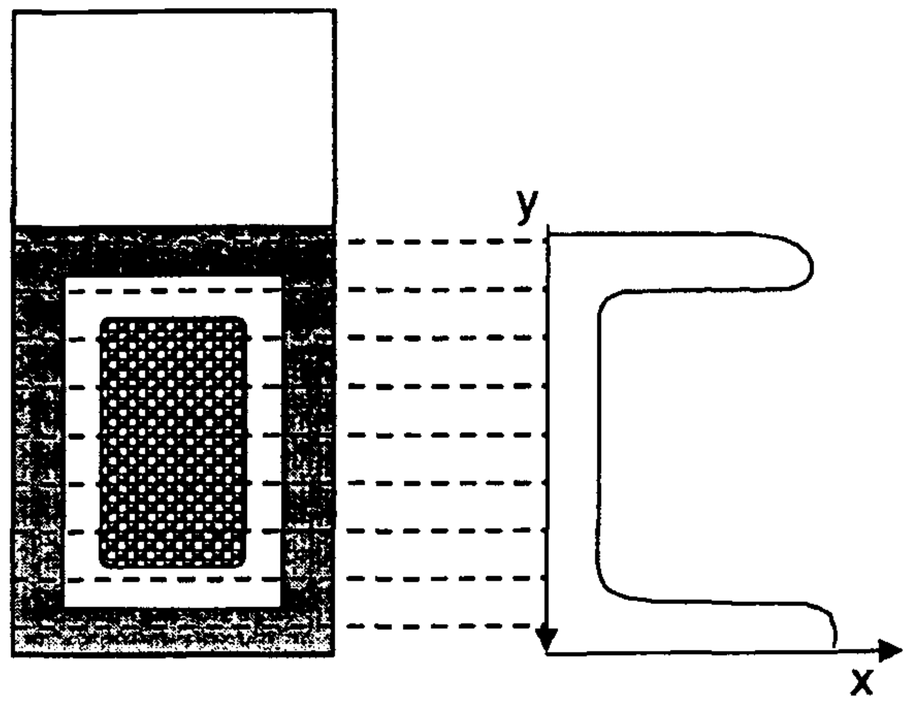


FIG. 3A

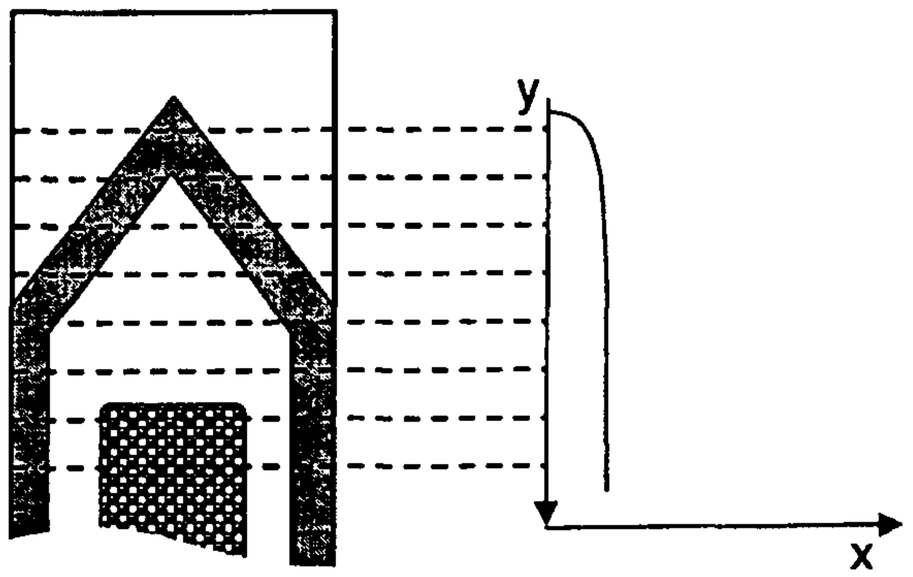


FIG. 3B

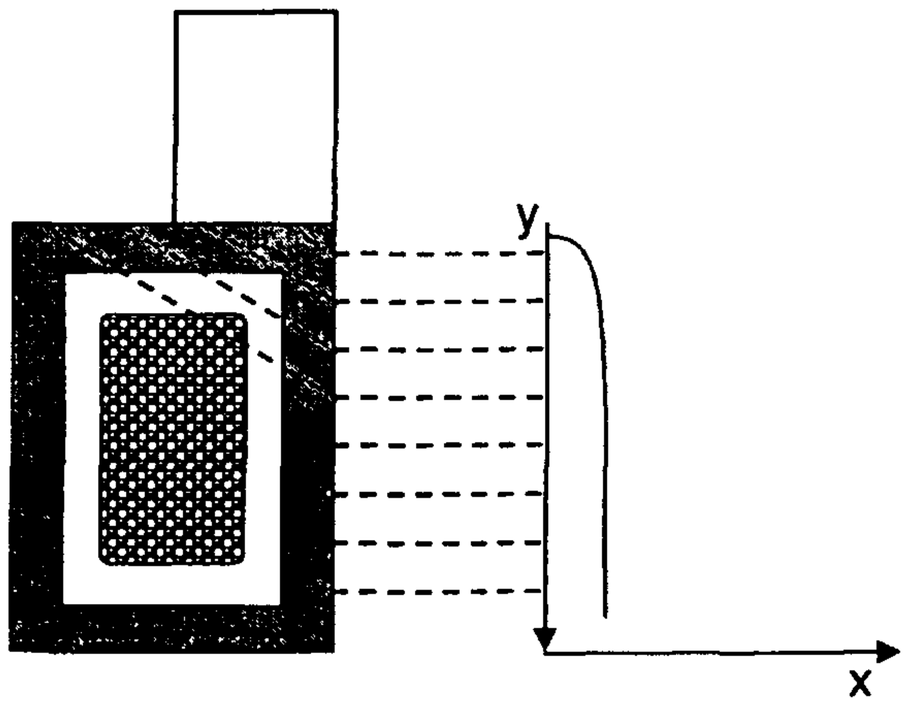
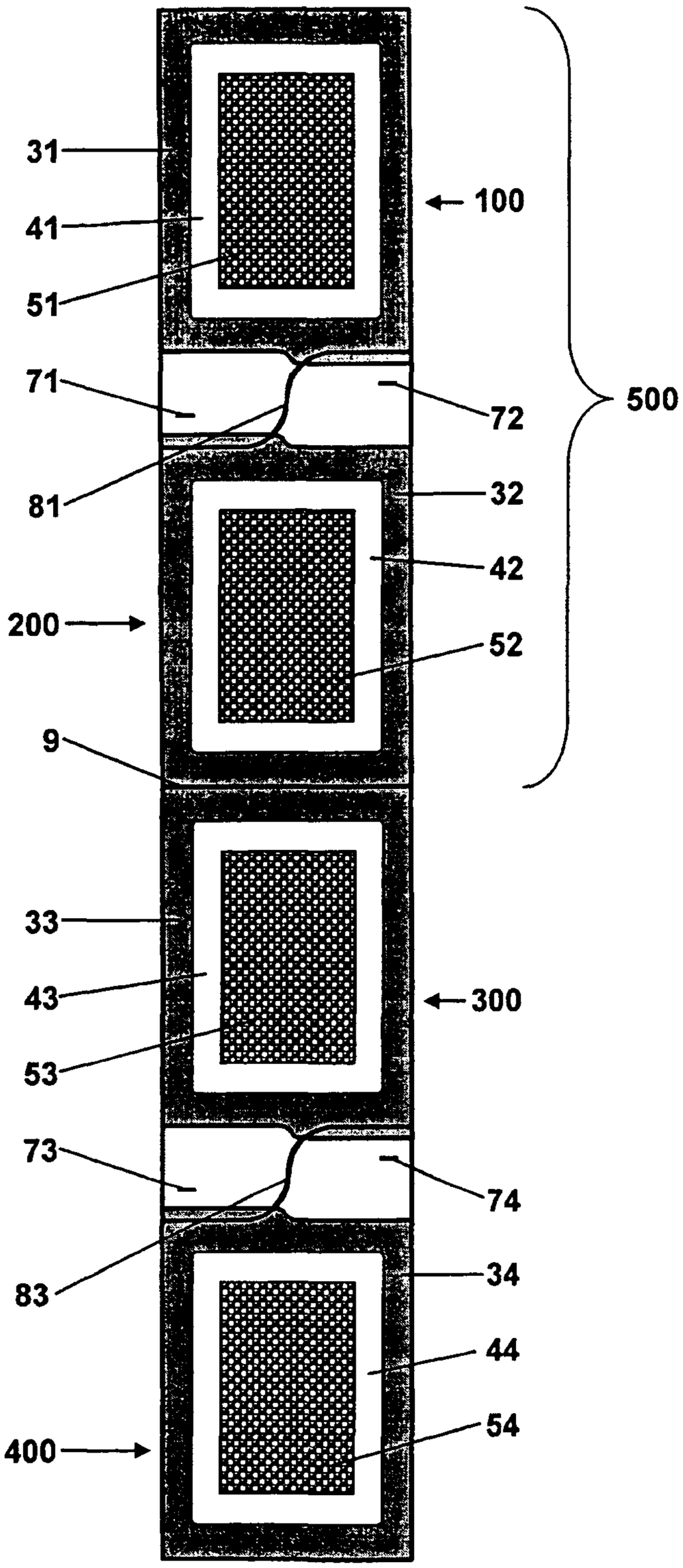


FIG. 3C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72
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54
100
500
300

FIG. 4

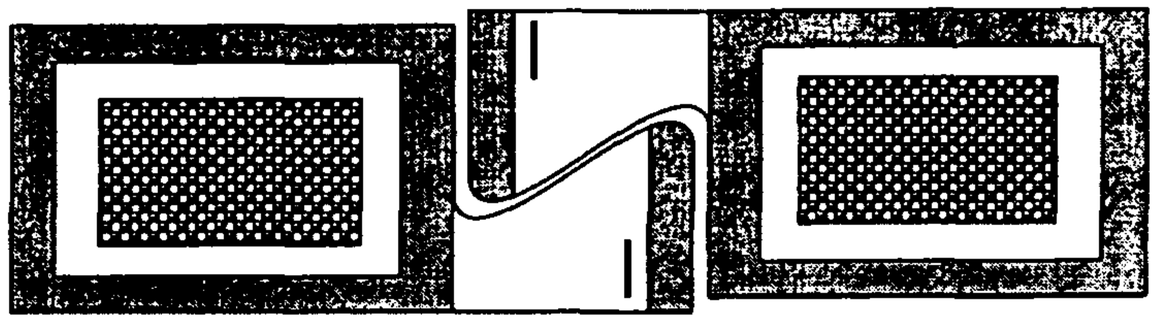


FIG. 5A

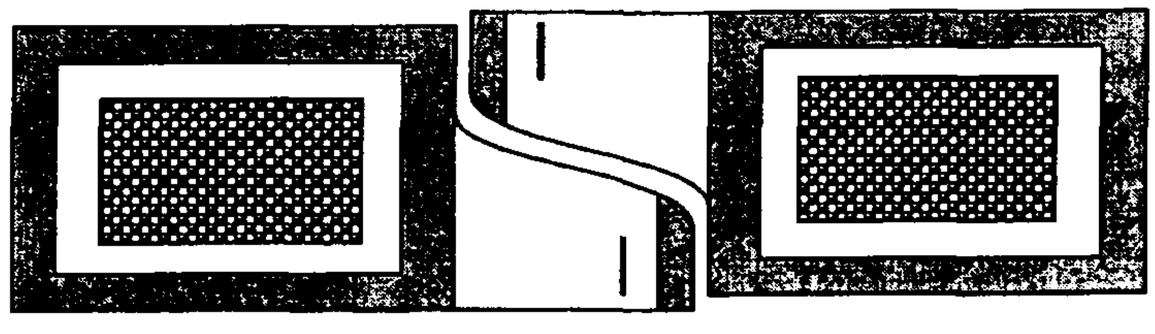


FIG. 5B

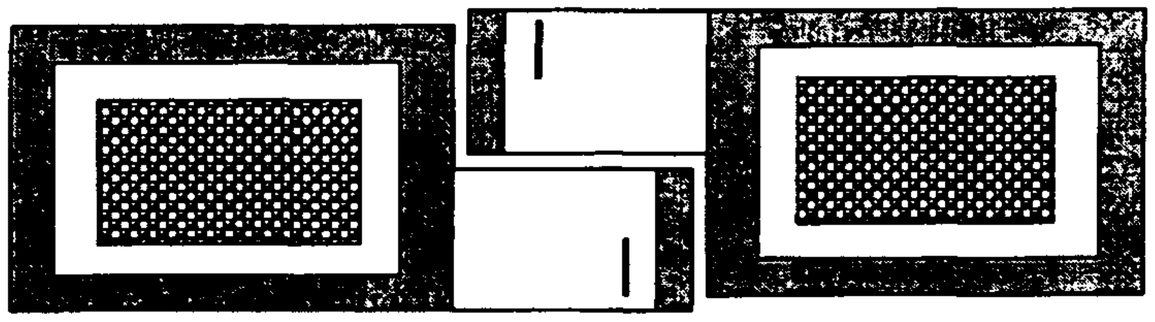


FIG. 5C

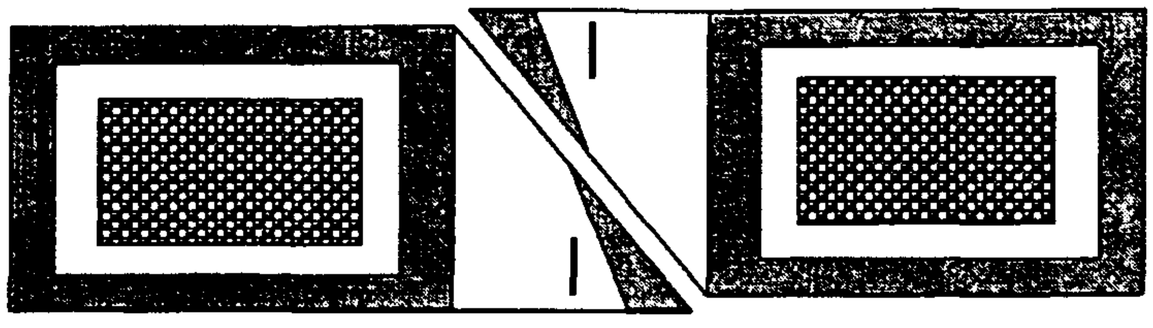


FIG. 5D

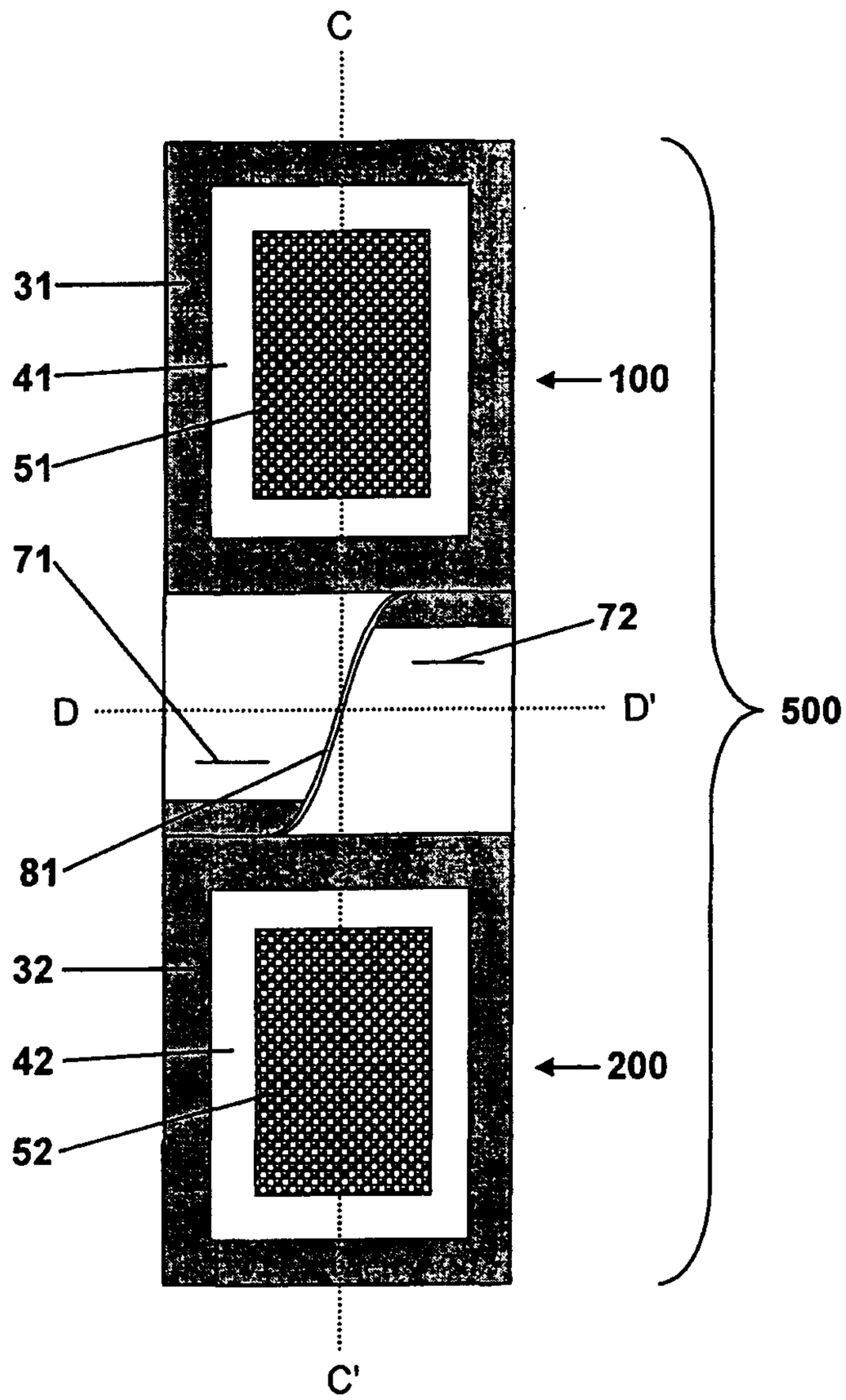
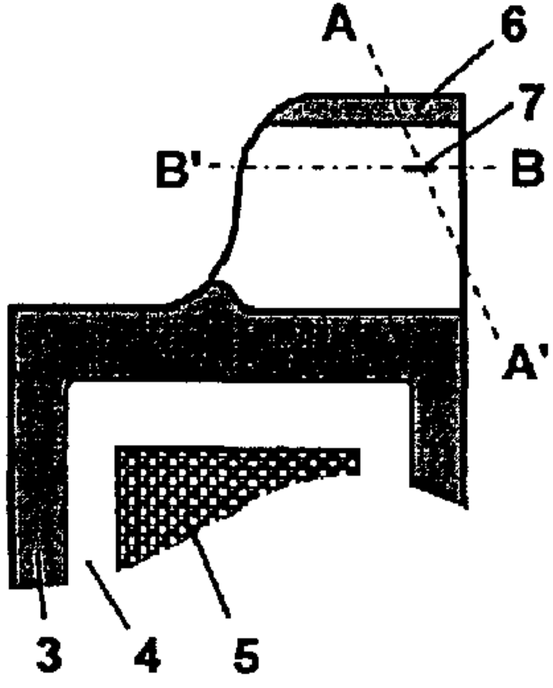
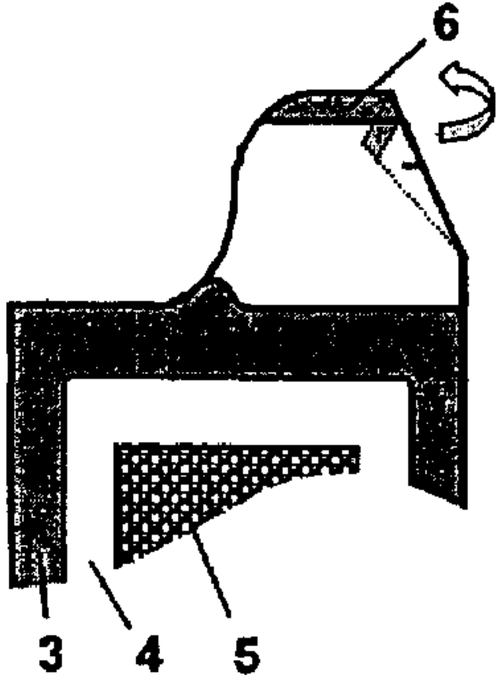


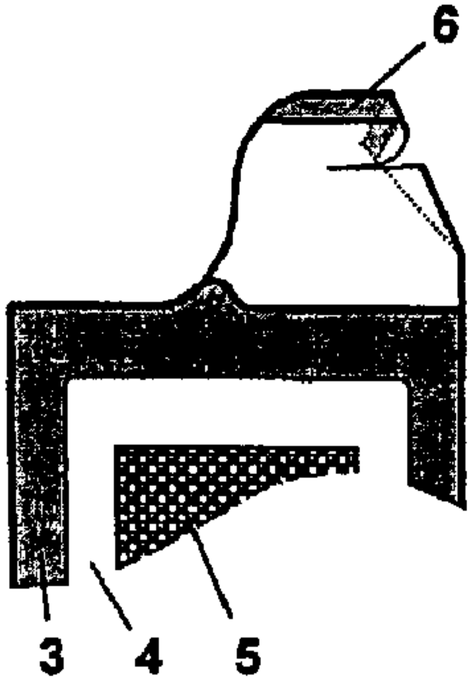
FIG. 6



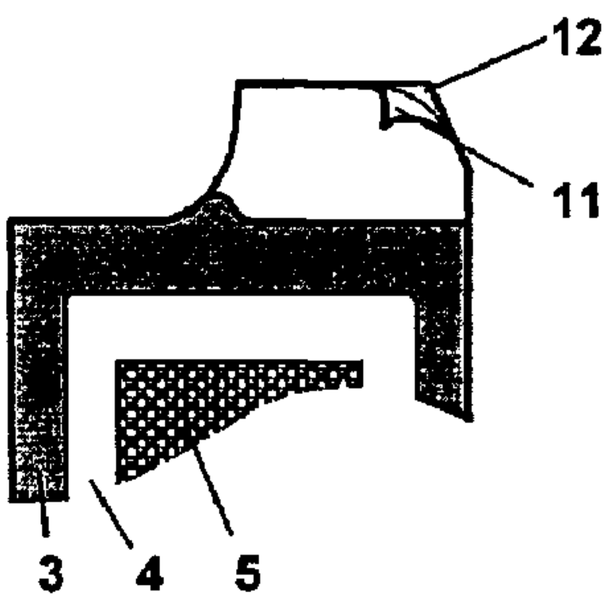
A



B



C



D