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(71) Applicant *(for all designated States except US)*: **R.P. SCHERER TECHNOLOGIES, INC.** [US/US]; 7690 Cheyenne Avenue, Suite 100, Las Vegas, NV 89129 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **BARNDT, David** [US/US]; a U.S. Citizen, 1170 Richlandtown Pike, Richlandtown, PA 18955 (US). **BERGEY, Michael, S.** [US/US]; a U.S. Citizen, 182A Taylorsville Road, Washington Crossing, PA 18977 (US). **GHERDAN, Victor** [US/US]; a U.S. citizen, 20 Kenwood Drive, Cherry Hill, NJ 08034 (US).

(74) Agent: **STEFFENSMEIER, Michael, D.**; Cardinal Health, Inc., 7000 Cardinal Place, Dublin, OH 43017 (US).

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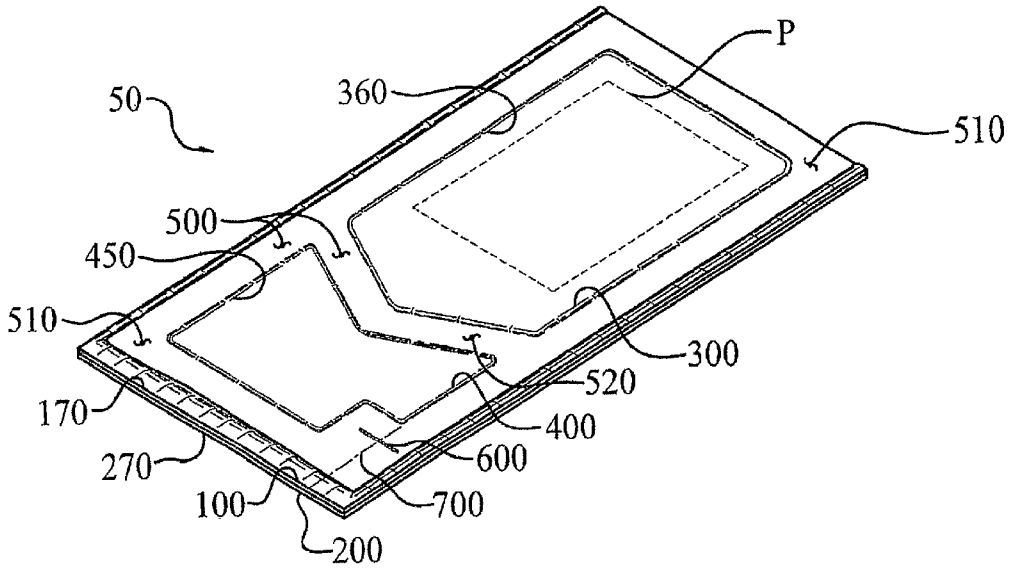
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(54) **Title:** IMPROVED PEELABLE POUCH CONTAINING A SINGLE FILM DOSAGE AND PROCESS OF MAKING SAME



(57) **Abstract:** A peelable pouch for containing a single dosage product having atop layer joined to a bottom layer by a containment seal and a distributing seal formed with a stress riser separating a primary compartment from a secondary compartment. The primary compartment houses the product, sealed from the exterior environment. The secondary compartment includes a fold-over line. When the pouch is folded about the fold-over line the tear promoting surface condition permits a user to easily tear off a portion of the pouch and expose a portion of the secondary compartment. The product is accessed by peeling apart the secondary compartment, the distributing seal, and then peeling open the primary compartment. Preferred embodiments incorporate variation in the primary and secondary containment seal thicknesses.

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IMPROVED PEELABLE POUCH CONTAINING A SINGLE FILM DOSAGE AND PROCESS OF MAKING SAME

Inventors: Barndt, et al.

REFERENCE TO RELATED DOCUMENTS

This application is related to a previous application filed in the United States Patent and Trademark Office by Paul H. Alvater and Thomas J. Fillis on August 2, 2004, entitled "PEELABLE POUCH CONTAINING A SINGLE OR MULTIPLE DOSAGE FORMS AND PROCESS OF MAKING SAME," and given serial number 10/910,675.

TECHNICAL FIELD

The instant invention relates to product packaging, and particularly to a process for forming a peelable pouch for individually housing single doses of a product, particularly for individually housing single doses of orally consumable film strips, and to the pouch formed thereby.

BACKGROUND OF THE INVENTION

Orally consumable films have become important consumer products for the dispensing of such substances as breath fresheners, anti-bacterial compounds, and various medicaments; and are frequently compounded with sweeteners, preservatives, and other additives. They are commonly made of water-soluble polymers, such as pullulan, as seen in U.S. Pat. Nos. 5,518,902; 5,411,945; and 4,851,394.

Presently, orally consumable films are generally distributed in reclosable packages containing ten or more doses. One dispenser adaptable for flat sheet orally consumable films is taught in U.S. Pat. Appl. Pub. No. 2003/0121932A1. This device uses a roller that can frictionally engage a flat article, such as an orally consumable strip, and dispense it through a slot in an otherwise closed container. An alternative packaging and dispensing system is seen

in U.S. Pat. Appl. Pub. No. 2003/0183643A1. In that device, the orally consumable films are contained in a blister pack having an openable back portion that opens and closes the blister pack by means of a resealable pressure sensitive adhesive area. Often such packages are very small and require the user to grip and remove the solid dosage product with a single index finger. To ease removal of such small, thin, lightweight products users often lick their finger to increase adhesion of the product to the finger. Obviously, such a procedure has a high probability of contaminating the other products in the packaging and has the potential of totally ruining the products from carryover saliva. Such a contact intensive removal and administration process is entirely unacceptable for medical products. Further, both the roller and resealable back blister pack have two serious drawbacks, namely, they are not particularly designed to prevent the dispensing of multiple sheets, nor do they have any child-resistant attributes.

These drawbacks may not be of much consequence in some of the frequent uses of orally consumable films, that is, for candy, breath aids, and the like. In this setting, dosage control and safety from accidental ingestion by children is not particularly important. Representative of these packages are those taught in U.S. Pat. No. 5,354,551. However, these films have been taught as methods of dosing drugs, as for example in U.S. Pat. No. 5,411,945. In such applications, dosage control and child resistance become essential qualities of any practical packaging.

Packaging of individually contained single dosage forms, including but not limited to orally consumable films, has become increasing popular. This is true with both pharmaceutical products as well as consumer products. One obvious advantage of this in the pharmaceutical market is that it substantially reduces the risk of accidental overdose.

Additionally, having the product individually wrapped, or housed, eliminates the risk of contaminating other doses of the product. Further, consumers appreciate the feeling obtained when opening an individually wrapped product because they know that they are the only one that has handled the actual product since it was packaged.

Some drawbacks come along with the benefits of individually packaged products. Perhaps the largest drawback and risk of individually packaged products is the risk posed to children. Individually wrapped products, especially small products such as medications, often resemble candy to a small child. Further, written warnings as to the contents are ineffective for children who cannot read. Most importantly, the vast majority of single dose packaging has not been child-resistant. As such, a demand for child-resistant single dose packaging has surfaced.

Present packaging technologies for individually wrapped candies and non-prescription products such as aspirin are particularly ineffective for the myriad of products that require some degree of child-resistant packaging because such candies and non-prescription product packaging has been designed solely for ease of opening. Additionally, an entirely new class of packaging is required for fast dispersing solid dosage products that are designed to dissolve when exposed to liquid. Most commonly, such fast dispersing solid dosage products are formed as a thin sheet, often less than a tenth of an inch in thickness, that is placed in the mouth to dissolve upon contact with saliva. This method of administration has become increasingly popular with prescription medications as well as consumer products such as breath fresheners. However, the key attribute that has made them popular, namely their dissolution upon contact with a liquid, has made them particularly susceptible to damage. Therefore, a process for forming individual, and individual child-resistant packaging for thin

sheet fast dispersing solid dosage products is particularly needed, as well as the need for the packaging itself.

To date, great attention has been focused on designing child-resistant blister packaging for tablet and capsule products. These packages have typically been formed of a rigid transparent top layer which is sealed or otherwise bonded to a backing layer in a manner that provides a cavity, pouch, or "blister" in which the medicament is disposed. Advances in such blister packaging have included the incorporation of features requiring peeling, folding, stripping, and/or rupturing of various portions of the packaging. Unfortunately the advances made in child-resistance for such packaging has little to no relevance to applications for thin sheet type products, particularly when such products are not rigid.

What has been needed, and heretofore unavailable, is a disposable, unit dose pouch for containing thin sheet type products that is child-resistant, yet senior-friendly, and allows for easy opening. Such a pouch must be inexpensive and easy to manufacture, maintain the integrity of the unit dose, and must be resistant to opening by children. At the same time, the package must be easily opened by an adult user that may have limited strength, coordination, or sight.

SUMMARY OF THE INVENTION

The instant invention provides a novel peelable pouch that addresses the shortcomings of the prior art. In its most general design, the pouch comprises a top layer joined to a bottom layer by at least one containment seal and at least one distributing seal, thereby creating a primary and a secondary compartment between the top layer and the bottom layer. The top layer has a peripheral edge and the bottom layer has a peripheral edge. The primary compartment houses the product (dosage form), sealed from the exterior environment, and is

formed between the top layer and the bottom layer by the top layer being selectively joined to the bottom layer by the containment and distributing seals. The secondary compartment is separated from the primary compartment by a distributing seal and may house a second product. For example, one can readily appreciate that the secondary compartment may house antibacterial hand washing solution that may be used to clean a user's hands prior to handling the product in the primary compartment.

The inventive peelable pouch also includes a tear promoting feature on the top layer and the bottom layer located substantially on a line that traverses a portion of the secondary compartment. When the pouch is folded about a fold-over line, the tear promoting surface condition or feature permits a user to easily tear off a portion of the top and bottom layers to expose a portion of the secondary compartment interior.

Once a portion of the secondary compartment has been exposed, the user pulls the top and bottom layers in opposing directions to peel the two layers apart separating the containment and distributing seals, following which, the product may then be removed from the primary compartment. In a preferred embodiment, the distributing seal is formed with at least two stress risers. In another embodiment, the containment seal is formed with variations in seal thickness. In this embodiment, the containment seal has a primary compartment seal and a secondary compartment seal with different thicknesses to provide child resistance and at the same time improve the ease with which the secondary and, therefore, the primary compartments may be opened.

Once a portion of the secondary compartment is exposed, a user may easily grip the top and bottom layers to peel them apart and separate the distributing seal thereby gaining access to the primary compartment and to the product. The secondary compartment enhances

the child-resistance of the pouch and improves the sterility of the packaging since at least two seals must be compromised before the product is exposed to the surrounding environment.

Thus, there is disclosed a peelable pouch for containing a single dosage product, comprising:

a top layer having a peripheral edge, an interior surface, an exterior surface, and a top layer width;

a bottom layer having a peripheral edge, an interior surface, an exterior surface, and a bottom layer width, wherein the top layer width and the bottom layer width are substantially the same;

a seal having a containment seal and a distributing seal, wherein the containment seal has two regions, (A) a primary compartment seal, having a primary compartment lateral seal thickness, and (B) a secondary compartment seal, having a secondary compartment lateral seal thickness, and wherein the distributing seal has a seal width and a distributing seal length; and wherein said distributing seal is formed with at least one stress riser having at least one initiation point;

a primary compartment housing the product, sealed from the exterior environment, formed between the top layer and the bottom layer by the top layer being selectively joined to the bottom layer by at least a portion of the containment seal and the distributing seal, the primary compartment having a peripheral boundary along a portion of the containment seal and a portion of the distributing seal, and having a primary compartment width ;

a secondary compartment formed between the top layer and the bottom layer by the top layer being selectively joined to the bottom layer by a portion of the containment seal and a portion the distributing seal, the secondary compartment being adjacent to the primary

compartment and separated from the primary compartment by the distributing seal, and the secondary compartment having a peripheral boundary along a portion of the containment seal and a portion of the distributing seal, and having a secondary compartment width ; the secondary compartment width is greater than the primary compartment width ; and

a tear promoting surface condition, on the top layer and the bottom layer, intersecting a fold-over line such that when the pouch is folded about the fold-over line the tear promoting surface condition permits a user to tear off a portion of the top layer and the bottom layer to expose a portion of the secondary compartment so that the user may grip the top layer and the bottom layer to peel them apart forming an opening in the primary compartment by separating the secondary compartment seal and the distributing seal, and gaining access to the product.

BRIEF DESCRIPTION OF THE DRAWINGS

Without limiting the scope of the present invention as claimed below and referring now to the drawings and figures:

FIG. 1 shows a representative peelable pouch in elevated perspective, not to scale;

FIG. 2 shows a top plan view of a representative peelable pouch, not to scale;

FIG. 3 shows a cross-sectional view taken along section line 3-3 in FIG. 2 of a peelable pouch, not to scale;

FIG. 4 shows a cross-sectional view taken along section line 4-4 in FIG. 3 of a peelable pouch, not to scale;

FIG. 5 shows a cross-sectional view taken along section line 5-5 in FIG. 3 of a peelable pouch, not to scale;

FIG. 6 shows a top plan view of an embodiment of the instant invention with a plurality of stress risers with substantially saw tooth shape, not to scale;

FIG. 7 shows a representative peelable pouch in elevated perspective view having an end portion folded and ready for tearing, not to scale;

FIG. 8 shows a representative peelable pouch partially torn in elevated perspective view, not to scale;

FIG. 9 shows a representative peelable pouch partially opened in elevated perspective view, not to scale;

FIG. 10 shows a representative peelable pouch partially opened in elevated perspective view, not to scale; and

FIG. 11 shows a top plan view of a representative peelable pouch, not to scale.

Also, in the various figures and drawings, the following reference symbols and letters are used to identify the various elements described herein below in connection with the figures and illustrations.

DETAILED DESCRIPTION OF THE INVENTION

The peelable pouch of the instant invention provides a significant advancement in the state of the art. The preferred embodiments of the inventive dosage delivery system accomplish this by new and novel arrangements of elements that are configured in unique and novel ways and which demonstrate previously unavailable but preferred and desirable capabilities. The detailed description set forth below in connection with the drawings is intended merely as a description of the presently preferred embodiments of the invention, and is not intended to represent the only form in which the present invention may be constructed or utilized. The description sets forth the designs, functions, means, and methods of

implementing the invention in connection with the illustrated embodiments. It is to be understood, however, that the same or equivalent functions and features may be accomplished by different embodiments that are also intended to be encompassed within the spirit and scope of the claims.

With reference now to FIG. 1, the instant invention is a peelable pouch (50) containing a single dosage product (P), preferably a fast dispersing film dosage form. The peelable pouch (50) includes a top layer (100) joined to a bottom layer (200) by a seal (500). The seal (500) is a continuous, unitary seal and is formed with two seal regions, namely, a containment seal (510) and a distributing seal (520). In FIG. 1, the containment seal (510) and distributing seal (520) are each shown as a continuous seal, by way of example only, and not limitation, as the seals may be separate. The containment seal (510) and distributing seal (520) create a primary compartment (300) and a secondary compartment (400) between the top layer (100) and the bottom layer (200), illustrated best in FIG. 1. The top layer (100) has a peripheral edge (170) and the bottom layer (200) has a peripheral edge (270). While the embodiments illustrated in the figures are generally rectangular in shape, one with skill in the art will recognize that the peripheral edges (170, 270) may be any shape.

The top layer (100) has an interior surface (110), in contact with the primary and secondary compartments (300, 400), and an exterior surface (120) in contact with the surrounding environment, shown best in FIG. 3. Similarly, the bottom layer (200) has an interior surface (210), in contact with the primary compartment (300) and the secondary compartment (400), and an exterior surface (220), in contact with the surrounding environment. The top layer (100) and the bottom layer (200) may be constructed of virtually any material. Embodiments of the pouch (50) directed to the medical market are typically

constructed of flexible laminated foil material, and may incorporate a peelable polymer. These foils or films are well known to those skilled in the art and are available commercially from a number of suppliers. Such materials may be impervious to moisture. Alternatively, embodiments directed toward non-prescription products for the mass market, such as breath films and other candies may be constructed of less expensive alternatives.

The primary compartment (300) houses the product (P), sealed from the exterior environment, and is formed between the top layer (100) and the bottom layer (200) by the top layer (100) being selectively joined to the bottom layer (200) by a portion of the containment seal (510) and the distributing seal (520), as seen in FIG. 1. Referring now to FIG. 6, the primary compartment (300) has a primary compartment width (370) and a primary compartment length (380), which are measured from a peripheral boundary (360). The peripheral boundary (360) is created by a portion of each of the containment and distributing seals (510, 520). As with the peripheral edges (170, 270), the peripheral boundary (360) of the primary compartment (300) may be any shape, including a shape designed to mimic the shape of the product (P), or a shape selected for ease of use in opening the pouch (50).

Similar to the primary compartment (300), the secondary compartment (400) is formed between the top layer (100) and the bottom layer (200) by the top layer (100) being selectively joined to the bottom layer (200) by portions of each of the containment and distributing seals (510, 520). Consequently, the secondary compartment (400) has a secondary compartment width (470), a secondary compartment length (480), and a peripheral boundary (450), which is created by portions of each of the containment and distributing seals (510, 520). The secondary compartment (400) is adjacent to the primary compartment (300) and separated from the primary compartment (300) by the distributing seal (520).

In the generic rectangular embodiment illustrated in FIGS. 1 through 10, the top layer (100) has a proximal edge (140), a distal edge (130), a first lateral edge (150), and a second lateral edge (160), as seen in FIG. 4. The distance from the first lateral edge (150) to the second lateral edge (160) defines a top layer width (180), and the distance from the proximal edge (140) to the distal edge (130) defines a top layer length (190), best illustrated in FIG. 4. Similarly, the bottom layer (200) has a proximal edge (240), a distal edge (230), a first lateral edge (250), and a second lateral edge (260). The distance from the first lateral edge (250) to the second lateral edge (260) define a bottom layer width (280), and the distance from the proximal edge (240) to the distal edge (230) defines a bottom layer length (290), best illustrated in FIG. 5. In an embodiment of the instant invention, the top and bottom layer widths (190, 290) are substantially the same, and the top and bottom layer lengths (190, 290) are substantially the same. Generally, the containment seal (510) joins the proximal edges (140, 240), the distal edges (130, 230), the first lateral edges (150, 250), and the second lateral edges (160, 260), of the top layer (100) and the bottom layer (200). The distributing seal (520) together with the containment seal (510), defines the primary compartment peripheral boundary (360) and secondary compartment peripheral boundary (450), as seen in FIGS. 1 and 6. In such a rectangular embodiment, best illustrated in FIG. 11, the primary compartment peripheral boundary (360) includes a proximal boundary (320), a distal boundary (310), a first lateral boundary (330), and a second lateral boundary (340). Likewise, the secondary compartment peripheral boundary (450) includes a proximal boundary (410), a first lateral boundary (430), a distal boundary (420), and a second lateral boundary (440). The containment seal (510), as illustrated in FIGS. 2 and 11, is generally a single continuous seal that separates the external environment from the primary and

secondary compartments (300, 400). The distributing seal (520) may be formed in a variety of shapes that cooperate to separate the primary and secondary compartments (300, 400).

With reference to FIGS. 2 and 11, the distributing seal (520) is formed by the joining of portions of the top and bottom layers (100, 200) and, as stated above, it separates the primary compartment (300) from the secondary compartment (400). As seen in FIG. 2, the distributing seal (520) has a seal length (524) and a distributing seal width (522), which is the shortest distance between the primary compartment distal boundary (320) and the secondary compartment proximal boundary (410). While the embodiments of the instant invention show a uniformly formed distributing seal (520) having a substantially uniform distributing seal width (522), it is not necessary that the distributing seal (520) have a substantially uniform distributing seal width (522). By way of example, and not limitation, a pouch (50) having a distributing seal (520) varying in width (522) is illustrated in FIG. 11. Those skilled in the art will appreciate the multitude of distributing seal (520) designs that are possible by variations in width, as well as, form. For example, an excursion, or excursions, on the surface of a seal, commonly known as a stress riser (526), may be formed in the distributing seal (520).

The stress riser (526) is shaped to have at least one initiation point (527). The initiation point (527) tends to create a peel starting region or regions on the distributing seal (520) during the process of opening the peelable pouch (50), discussed in more detail later. At the initiation point, or points, (527), the distributing seal (520) begins its opening response, or peel, to the tensile stresses created by pulling the top and bottom layers (100, 200) apart. Generally, the opening response occurs on the side of the distributing seal (520) in which the initiation point (527) is located. The separation of the top and bottom layers

(100, 200) eventually reaches the distributing seal (520) with the initiation point (527). By continued application of opposing forces to each of the top and bottom layers (100, 200), which tend to pull the layers (100, 200) apart, tensile stresses are focused at the initiation point (527) rather than diffusely spreading the tension along the distributing seal length (524). The stress riser (526) is oriented to extend the initiation point (527) in the direction of the oncoming separation line between top and bottom layers (100, 200) as the layers (100, 200) are forcibly pulled apart. In other words, at the distributing seal (520), initial separation of the top layer (100) from the bottom layer (200) occurs at the initiation point (527). By concentrating the applied forces at one or more initiation points (527), rather than across the entire distributing seal (520), less force is required to initiate the separation of the distributing seal (520). Therefore, the separation of the top and bottom layers (100, 200) of the distributing seal (520) proceeds more predictably and consistently and ultimately requires less finger, wrist, and forearm strength.

In embodiments of the instant invention, the stress riser (526) has a substantially saw tooth shape where the initiation point (527) is the region substantially along the tip of the tooth, as seen in FIGS. 2 and 11. However, it is not necessary that the stress riser (526) have any particular configuration, only that the initiation of seal opening, or peel, is enhanced as the initiation point (527) of the stress riser (526) becomes sharper. In one embodiment of the instant invention, as seen in FIG. 6, the distributing seal (520) is formed with a plurality of saw tooth shaped stress risers (526).

The selection of an optimal design of the stress riser (526) or risers might be selected to reflect particular characteristics of the product (P) contained in the primary compartment (300) or the polymer covered foil material. The containment and the distributing seal (510,

520) may be created by virtually any material joining technology. Most commonly, the containment and distributing seals (510, 520) will be at least one fusion seal created under elevated temperature and pressure; however, they may also be a mechanical or chemical seal. Such a mechanical seal could include, by way of example and not limitation, crimping and various retainer clips; and such thermal or chemical seals could include, by way of example and not limitation, adhesive bonds such as chemical adhesive or hot melt techniques, or other fusion methods. The containment and distributing seals (510, 520) are selected to be strong enough that they cannot be easily separated by a small child, yet can be opened without difficulty by the elderly.

Further, while the top (100) and bottom (200) layers have been illustrated and described as separate distinct articles, one with skill in the art will recognize that the top layer (100) and the bottom layer (200) may be formed from a common substrate folded over at either the proximal edges (140, 240), the distal edges (130, 230), the first lateral edges (150, 250), or the second lateral edges (160, 260), creating a folded edge thereby not requiring the containment seal (510) along the folded edge. In such an embodiment, the three containment seal (510) edges, the distributing seal (520), and the folded edge define the primary compartment peripheral boundary (360).

The peelable pouch (50) also includes a tear promoting surface condition (600) on the top layer (100) and the bottom layer (200) located substantially near a fold-over line (700). The fold-over line (700) generally intersects, and is substantially orthogonal to, the tear promoting surface condition (600), and is illustrated in FIGS. 1 and 6. When the pouch (50) is folded about the fold-over line (700), as seen in FIG. 7, the tear promoting surface condition (600) is presented and permits a user to easily upturn a portion of the pouch (50), as

seen in FIG. 8. The upturned portion may then be easily grasped and pulled to tear off a portion of the top (100) and bottom (200) layers to expose a portion of the secondary compartment (400), as seen in FIG. 9.

Child-resistance is provided by the pouch (50) in that it may be easily torn only once simultaneous or complex movement sequences have been performed, which would not be obvious to a small child. For instance, the pouch (50) is exceedingly difficult to tear open without first folding it along the fold-over line (700) and exposing the tear promoting surface condition (600). In one embodiment, the tear promoting surface condition (600) is a tear slit (610) that extends through the top layer (100) and the bottom layer (200) in an area of the seal containment seal (510). Alternatively, the tear promoting surface condition (600) may simply be an indentation in the surface of the top and bottom layers (100, 200), a penetration of any shape extending through the top and bottom layers (100, 200), areas of reduced thickness of the top and bottom layers (100, 200), or areas of different material formed in the top and bottom layers (100, 200). The tear promoting condition (600) could also encompass a tear string or other integral tearing structure, as would be known to one skilled in the art.

The fold-over line (700) may be identified on the pouch (50) in any of a number of ways. First, the fold-over line (700) may not be expressly identified at all, but rather be implicitly identified by the location and orientation of the tear promoting surface condition (600). For instance in the embodiment of FIG. 1, most adults would recognize that the tear promoting surface condition (600) that does not extend all the way to an edge would most easily be accessed by folding the pouch (50) lengthwise, or substantially orthogonal to the tear promoting surface condition (600), as seen in FIG. 7. Alternatively, the pouch (50) may further include indicia (710) located substantially on the fold-over line (700) to indicate how

to fold the pouch (50). Such indicia (710) may simply be a line as shown in FIG. 1, or may incorporate a written message such as "fold along line and tear," as seen in FIG. 6.

The tear promoting surface condition (600) is configured to promote a tear across a portion of the secondary compartment (400). Therefore, when the pouch (50) is folded about the fold-over line (700), as seen in FIG. 7, the tear promoting surface condition (600) presents itself and permits a user to fold the end of the pouch (50) so that it may be easily gripped, as seen in FIG. 8. The user may then easily tear off a portion of the top (100) and bottom (200) layers to expose a portion of the secondary compartment (400), illustrated in FIG. 10. Once a portion of the secondary compartment (400) is exposed, a user may easily grip the top layer (100) and the bottom layer (200) to peel them apart, thereby separating the secondary compartment seal (516) followed by separation of the distributing seal (520).

In an embodiment of the instant invention, the secondary compartment width (470) is at least 0.25 inches and sized to permit the user to catch the exposed top and bottom layers (100, 200) with a raking or picking motion made in opposing directions with two digits, most likely their two thumbs. The user can then initiate separation of the secondary compartment seal (516) which ultimately permits the user to pincher grip the top layer (100) between one or more fingers and thumb on one hand and the bottom layer (200) between one or more fingers and thumb on the other hand. By separating the distributing seal (520), the user creates an opening in the primary compartment (300), thereby gaining access to the product (P). The secondary compartment (400) enhances the child-resistance of the pouch (50) and improves the sterility of the packaging since at least two seals must be compromised before the product (P) is exposed to the surrounding environment.

The separation of the product (P) in the primary compartment (300) from the secondary compartment (400) permits the incorporation of perforations (720) across the secondary compartment (400) in the preferred location for the tear, as illustrated in FIG. 6. Such perforations (720) make the tear easier to perform and provide enhanced control over the location of the tear. The perforations (720) may extend through the top layer (100) and the bottom layer (200) permitting the exterior atmosphere to enter the secondary compartment (400) while the product (P) in the primary compartment (300) remains sealed and protected from potential contaminants.

In another embodiment of the instant invention, as seen in FIG. 6, the containment seal (510) varies in thickness by compartment. In this embodiment, the containment seal (510) has a primary compartment seal (512) having a lateral seal thickness (513) and a proximal seal thickness (514). The containment seal (510) also has a secondary compartment seal (516) having a lateral seal thickness (517) and a distal seal thickness (518). In FIG. 6, each seal region (512, 516, 520) is generally identified. By forming the primary compartment seal (512) of different thickness than the secondary compartment seal (516), varying degrees of child resistance can be realized. By way of example and not limitation, in an embodiment of the present invention the secondary compartment lateral seal thickness (517) is less than the primary compartment lateral seal thickness (513), as seen in FIG. 6. The advantages of this containment seal (510) design are two-fold.

First, the child resistance of the primary compartment (300) is substantially the same as the embodiment of the instant invention where the primary compartment lateral seal thickness (513) and the secondary compartment lateral seal thicknesses (517) are substantially the same. And, secondly, the secondary compartment (516) may be opened

more easily versus the embodiment of the instant invention where the primary compartment and secondary lateral seal thicknesses (513,517) are substantially the same. A reduction in the secondary compartment lateral seal thickness (517) may reduce the force required to separate the secondary compartment seal (516) because the reduced secondary compartment lateral seal thickness (517) reduces the total secondary compartment seal (516) area. In addition, a reduction in the secondary compartment lateral seal thickness (517) increases the secondary compartment width (470). In other words, less seal may allow the user to grip the open end of the secondary compartment (400) more easily and, consequently, may allow the user to peel the secondary compartment (400) open more easily. In an embodiment of the instant invention, the secondary compartment lateral seal thickness (517) is between approximately 0.062 inches (0.15748 cm) and 0.5 inches (1.27 cm) and the secondary compartment width (470) is between approximately 0.25 (0.0635 cm) inches to approximately 3.0 inches (7.62 cm). The primary compartment lateral seal thickness (513) is between about 0.125 inches (0.3175 cm) and about 0.562 inches (1.42748 cm). The distributing seal width (522) is between 0.062 inches (0.15748 cm) to 0.25 inches (1.27 cm) wide.

In an embodiment of the instant invention, the secondary compartment (400) may house a second product. For example, one can readily appreciate that the secondary compartment (400) may house an antibacterial hand washing solution that may be used to clean a user's hands prior to handling the product (P) in the primary compartment (300).

The Inventors will now disclose how the pouch (50) described above may be part of a process to place single dosage forms of a wide variety of product types, in primary compartments. Such a process would, overall, utilize the steps of providing bulk single

dosage product while concurrently providing two opposing sheets of pouch material in a suitable packaging machine. A plurality of single dosage products (P) would be placed between the two opposing sheets of pouch material comprising a top layer (100) and bottom layer (200) in a predetermined pattern, creating areas wherein the top layer (100) and bottom layer (200) of pouch material are separated by single dosage product (P) and areas where the top layer (100) and bottom layer (200) of pouch film material may directly touch.

The pouches containing the single dosage product (P) would be formed by applying sealing means to a portion of the top layer (100) and bottom layer (200) of pouch film material such that sealing will occur in areas where top layer (100) and bottom layer (200) of pouch material may directly touch. The result would be to seal a portion of the top layer (100) and bottom layer (200) of pouch material to enclose at least one of a plurality of the single dosage products (P) in at least one closed pouch, sealed from the environment, thereby creating a plurality of closed pouches further comprising a secondary compartment (400) and a primary compartment (300) containing the single dosage product (P). The sealing means may be a thermal means, or any of a variety of sealing techniques that would be known to one skilled in the art.

The remaining stages of the process may include forming a tear promoting surface condition (600) in each of the plurality of closed pouches to aid in the later opening of the pouches, and then cutting the plurality of closed pouches into a plurality of individual closed pouches (50). The plurality of individual closed pouches (50) could then be discharged, ready for secondary packaging. The order of the steps of the process may be varied somewhat, as would be apparent to one skilled in the art. By way of example and not

limitation, the tear promoting surface condition (600) could be formed either before or after the sealing step.

The tear promoting surface condition (600) may further be formed with a fold-over line (700) that intersects the tear promoting condition (600) such that when the pouch (50) is folded along the fold-over line (700) the tear promoting surface condition (600) presents itself to a user so that it can be easily folded back, as seen in FIG. 7, for easy gripping. The tear promoting surface condition (600) permits a user to easily tear off a portion of the top (100) and bottom layer (200) and expose a portion of the secondary compartment (400). The location of the fold-over line (700) may be based upon the type of tear promoting surface condition (600) that is incorporated into the pouch (50), as well as the desired level of child-resistance.

The process may further include the step of imprinting indicia on the single dosage product (P) before sealing, as well as further including the step of imprinting indicia (710) on the pouch material either before or after sealing. Indicia (710) imprinted on the pouch material could identify the tear promoting surface condition. Indicia (710) may also identify the product (P) should the individual pouches (50) be separated from the secondary packaging, while indicia imprinted on the single dosage product (P) itself could serve as a safety check for the consumer before use and as a reassurance that the product (P) had been properly identified during packaging.

The pouch (50) as detailed above may be further contemplated as an embodiment for sealing single dosage film strips of orally consumable film in individual pouches. Such a process may involve the steps of first providing bulk orally consumable film strip cast in roll form, and then unwinding the orally consumable film strip under tension in a suitable

machine. The roll form may further be formed of a laminate comprising an orally consumable film strip and a paper backing wherein the film strip and paper backing are simultaneously unwound.

The bulk film strip may then be slit or otherwise cut into a plurality of strips of lesser width, and each of the strips may then be cut into a plurality of single dosage film strips, each representing a single dosage product (P).

The process may then concurrently provide two opposing sheets of pouch material comprising a top layer (100) and bottom layer (200) and placing a plurality of single dosage film strips between the top layer (100) and bottom layer (200) of pouch material in a predetermined pattern. The pattern could create areas wherein the top layer (100) and bottom layer (200) of pouch film material are separated by single dosage film strips and areas where the top layer (100) and bottom layer (200) of pouch film material may directly touch.

The application of sealing means to a portion of the top layer (100) and bottom layer (200) in areas where the top layer (100) and bottom layer (200) of pouch material are directly touching will create a pouch to enclose the single dosage film strip. The sealing means may be a thermal means.

The remaining stages of the process includes forming a tear promoting surface condition (600) in each of the closed pouches and then cutting the plurality of closed pouches into a plurality of individual closed pouches (50). The plurality of individual closed pouches (50) will then be discharged and ready for secondary packaging. The order of the steps of the process may be varied somewhat, as would be apparent to one skilled in the art. By way of example and not limitation, the tear promoting surface condition (600) could be formed either before or after the sealing step.

The tear promoting surface condition (600) may further be formed of a feature on the top layer (100) and the bottom layer (200). The tear promoting surface condition (600) may be configured so that a tear that originates therefrom traverses a portion of the primary compartment (300) thereby removing a portion of the top (100) and bottom layer (200) to expose a portion of the primary compartment (300). The fold-over line (700) may intersect the tear promoting surface condition (600) at virtually any angle despite the figures illustrating the intersection as substantially orthogonal.

The process may further include the step of imprinting indicia on the single dosage film strip before sealing as well as further including the step of imprinting indicia (710) on pouch material either before or after sealing. Indicia (710) imprinted on the pouch material could identify the dosage form should the individual pouches be separated from the secondary packaging, while indicia imprinted on the single dosage film strip itself could serve as a safety check for the consumer.

INDUSTRIAL APPLICABILITY

The peelable pouch according to the present invention answers a long felt need for a low cost disposable package for housing a single film dosage form. The present invention provides a package that offers simplicity in manufacture, convenience in storage, preservation of product, resistance to contamination, child-resistance, and improved sanitation. In particular, the inventive package has the capacity to provide a means for safely delivering thin film dosage forms while at the same time creating efficient child resistant packaging.

Numerous alterations, modifications, and variations of the preferred embodiments disclosed herein will be apparent to those skilled in the art and they are all anticipated and contemplated to be within the spirit and scope of the instant invention. For example, although specific embodiments have been described in detail, those with skill in the art will understand that the preceding embodiments and variations can be modified to incorporate various types of substitute and/or additional or alternative materials, relative arrangement of elements, and dimensional configurations.

WE CLAIM:

1. A peelable pouch (50) for containing a single dosage product (P), comprising:

a top layer (100) having a peripheral edge (170), an interior surface (110), an exterior surface (120), and a top layer width (180);

a bottom layer (200) having a peripheral edge (270), an interior surface (210), an exterior surface (220), and a bottom layer width (280), wherein the top layer width (180) and the bottom layer width (280) are substantially the same;

a seal (500) having a containment seal (510) and a distributing seal (520), wherein the containment seal (510) has two regions, (A) a primary compartment seal (512), having a primary compartment lateral seal thickness (513), and (B) a secondary compartment seal (516), having a secondary compartment lateral seal thickness (517), and wherein the distributing seal (520) has a seal width (522) and a distributing seal length (524); and wherein said distributing seal (50) is formed with a stress riser (526) that is saw tooth-shaped;

a primary compartment (300) housing the product (P), sealed from the exterior environment, formed between the top layer (100) and the bottom layer (200) by the top layer (100) being selectively joined to the bottom layer (200) by at least a portion of the containment seal (510) and the distributing seal (520), the primary compartment (300) having a peripheral boundary (360) along a portion of the containment seal (510) and a portion of the distributing seal (520), and having a primary compartment width (370);

a secondary compartment (400) formed between the top layer (100) and the bottom layer (200) by the top layer (100) being selectively joined to the bottom layer (200) by a portion of the containment seal (510) and a portion the distributing seal (520), the secondary compartment (400) being adjacent to the primary compartment (300) and separated from the

primary compartment (300) by the distributing seal (520), and the secondary compartment (400) having a peripheral boundary (450) along a portion of the containment seal (510) and a portion of the distributing seal (520), and having a secondary compartment width (470); the secondary compartment width (470) is greater than the primary compartment width (370); and

a tear promoting surface condition (600), on the top layer (100) and the bottom layer (200), intersecting a fold-over line (700) such that when the pouch (50) is folded about the fold-over line (700) the tear promoting surface condition (600) permits a user to tear off a portion of the top layer (100) and the bottom layer (200) to expose a portion of the secondary compartment (400) so that the user may grip the top layer (100) and the bottom layer (200) to peel them apart forming an opening in the primary compartment (300) by separating the secondary compartment seal (516) and the distributing seal (520), and gaining access to the product (P).

2. The pouch (50) of claim 1, wherein the initiation point (527) is located on the secondary compartment peripheral boundary (450).

3. The pouch (50) of claim 1, wherein the secondary compartment width (470) is sized to cooperate with two human digits.

4. The pouch (50) of claim 1, wherein the secondary compartment width (470) is between approximately 0.25 inches (0.635 cm) and approximately 3.0 inches (7.62 cm).

5. The pouch (50) of claim 1, wherein the secondary compartment lateral seal thickness (517) is substantially the same as the primary compartment lateral seal thickness (513).

6. The pouch (50) of claim 5, wherein the secondary compartment lateral seal thickness (517) and the primary compartment lateral seal thickness (513) are between approximately 0.062 inches (0.15748 cm) and approximately 0.5 inches (1.27 cm).

7. The pouch (50) of claim 1, wherein the secondary compartment lateral seal thickness (517) is less than the primary compartment lateral seal thickness (513).

8. The pouch (50) of claim 7, wherein the secondary compartment lateral seal thickness (517) is between approximately 0.062 inches (0.15748 cm) and approximately 0.5 (1.27 cm) inches and the primary compartment lateral seal thickness (513) is between approximately 0.125 inches (0.3175 cm) and approximately 0.562 inches (1.42748 cm).

9. The pouch (50) of claim 1, wherein the distributing seal width (522) is substantially uniform.

10. The pouch (50) of claim 9, wherein the distributing seal width (522) is between 0.062 inches (0.15748 cm) to 0.25 inches (1.27 cm) wide.

11. The pouch (50) of claim 1, wherein the distributing seal width (522) varies over the distributing seal length (524).

12. The pouch (50) of claim 1, wherein the top layer (100) has a proximal edge (130), a distal edge (140), a first lateral edge (150), and a second lateral edge (160), the bottom layer (200) has a proximal edge (230), a distal edge (140), a first lateral edge (150), and a second lateral edge (160), and wherein the top layer (100) and the bottom layer (200) are formed from a common substrate folded over at either the proximal edge (100), the distal edge (140), the first lateral edge (150), or the second lateral edge (160) creating a folded edge thereby not requiring the containment seal (510) along the folded edge, whereby the containment seal (510), the distributing seal (520), and the folded edge define the primary compartment peripheral boundary (360) to include a proximal boundary (310), a distal boundary (320), a first lateral boundary (330), and a second lateral boundary (340), and define the secondary compartment peripheral boundary (450) to include a proximal boundary (410), a distal boundary (420), a first lateral boundary (430), and a second lateral boundary (440), wherein once the secondary compartment distal boundary (420) is torn away, a user may easily grip the top layer (100) and the bottom layer (200) to peel them apart to separate the secondary compartment seal (516) and the distributing seal (520), thereby gaining access to the product.

13. The pouch (50) of claim 1, further including a second product housed in the secondary compartment (400).

14. A peelable pouch (50) for containing a single dosage product (P), comprising:

a top layer (100) having a peripheral edge (170), an interior surface (110), an exterior surface (120), and a top layer width (180);

a bottom layer (200) having a peripheral edge (270), an interior surface (210), an exterior surface (220), and a bottom layer width (280), wherein the top layer width (180) and the bottom layer width (280) are substantially the same;

a seal (500) having a containment seal (510) and a distributing seal (520), wherein the containment seal (510) has two regions, (A) a primary compartment seal (512), having a primary compartment lateral seal thickness (513), and (B) a secondary compartment seal (516), having a secondary compartment lateral seal thickness (517), and wherein the distributing seal (520) has a seal width (522) that is substantially uniform with a stress riser (526) and is saw tooth-shaped, and wherein the secondary compartment lateral seal thickness (517) is less than the primary compartment lateral seal thickness (513);

a primary compartment (300) housing the product (P), sealed from the exterior environment, formed between the top layer (100) and the bottom layer (200) by the top layer (100) being selectively joined to the bottom layer (200) by the primary compartment seal (512) and the distributing seal (520), the primary compartment (300) having a peripheral boundary (360) along a portion of the primary compartment seal (512) and a portion of the distributing seal (520), and having a primary compartment width (370);

a secondary compartment (400) formed between the top layer (100) and the bottom layer (200) by the top layer (100) being selectively joined to the bottom layer (200) by a portion of the secondary compartment seal (516) and a portion of the distributing seal (520), the secondary compartment (400) being adjacent to the primary compartment (300) and is separated from the primary compartment (300) by the distributing seal (520), the secondary compartment (400) having a peripheral boundary (450) along a portion of the secondary compartment seal (516) and a portion of the distributing seal (520) and wherein the initiation

point (527) is located on the secondary compartment peripheral boundary (450), and the secondary compartment (400) having a secondary compartment width (470) wherein the secondary compartment width (470) is greater than the primary compartment width (370); and

a tear promoting surface condition (600), on the top layer (100) and the bottom layer (200), intersecting a fold-over line (700) such that when the pouch (50) is folded about the fold-over line (700) the tear promoting surface condition (600) permits a user to easily tear off a portion of the top layer (100) and the bottom layer (200) to expose a portion of the secondary compartment (400) so that the user may easily grip the top layer (100) and the bottom layer (200) to peel them apart forming an opening in the primary compartment (300) by separating the secondary compartment seal (516) and the distributing seal (520), and gaining access to the product (P).

15. A peelable pouch (50) for containing a single dosage product (P), comprising:

a top layer (100) having a peripheral edge (170), an interior surface (110), an exterior surface (120), and a top layer width (180);

a bottom layer (200) having a peripheral edge (270), an interior surface (210), an exterior surface (220), and a bottom layer width (280), wherein the top layer width (180) and the bottom layer width (280) are substantially the same;

a seal (500) having a containment seal (510) and a distributing seal (520), wherein the containment seal (510) has two regions, (A) a primary compartment seal (512), having a primary compartment lateral seal thickness (513), and (B) a secondary compartment seal (516), having a secondary compartment lateral seal thickness (517), and wherein the

distributing seal (520) has a seal width (522) that is substantially uniform between approximately 0.125 inches and approximately 0.25 inches and is formed with a stress riser (526) having a substantially saw tooth shape with at least two initiation points (527), and wherein the secondary compartment lateral seal thickness (517) is less than the primary compartment lateral seal thickness (513) which is between approximately 0.062 inches and approximately 0.5 inches;

a primary compartment (300) housing the product (P), sealed from the exterior environment, formed between the top layer (100)) and the bottom layer (200) by the top layer (100) being selectively joined to the bottom layer (200) by the primary compartment seal (512) and the distributing seal (520), the primary compartment (300) having a peripheral boundary (360) along a portion of the primary compartment seal (512) and a portion of the distributing seal (520), and having a primary compartment width (370);

a secondary compartment (400) formed between the top layer (100) and the bottom layer (200) being selectively joined to the bottom layer (200) by a portion of the secondary compartment seal (516) and a portion of the distributing seal (520), the secondary compartment (400) being adjacent to the primary compartment (300) and is separated from the primary compartment (300) by the distributing seal (520), the secondary compartment (400) having a peripheral boundary (450) along a portion of the secondary compartment seal (516) and a portion of the distributing seal (520) and wherein the initiation point (527) is located on the secondary compartment peripheral boundary (450), the secondary compartment (400) having a secondary compartment width (470) that is between approximately 1.0 inches and approximately 2.0 inches and the secondary compartment width (470) is greater than the primary compartment width (370); and

a tear promoting surface condition (600), on the top layer (100) and the bottom layer (200), intersecting a fold-over line (700) including indicia (710) substantially on the fold-over line (700) such that when the pouch (50) is folded about the fold-over line (700) the tear promoting surface condition (600) permits a user to easily tear off a portion of the top layer (100) and the bottom layer (200) to expose a portion of the secondary compartment (400) so that the user may easily grip the top layer (100) and the bottom layer (200) to peel them apart forming an opening in the primary compartment (300) by separating the secondary compartment seal (516) and the distributing seal (520), and gaining access to the product (P).

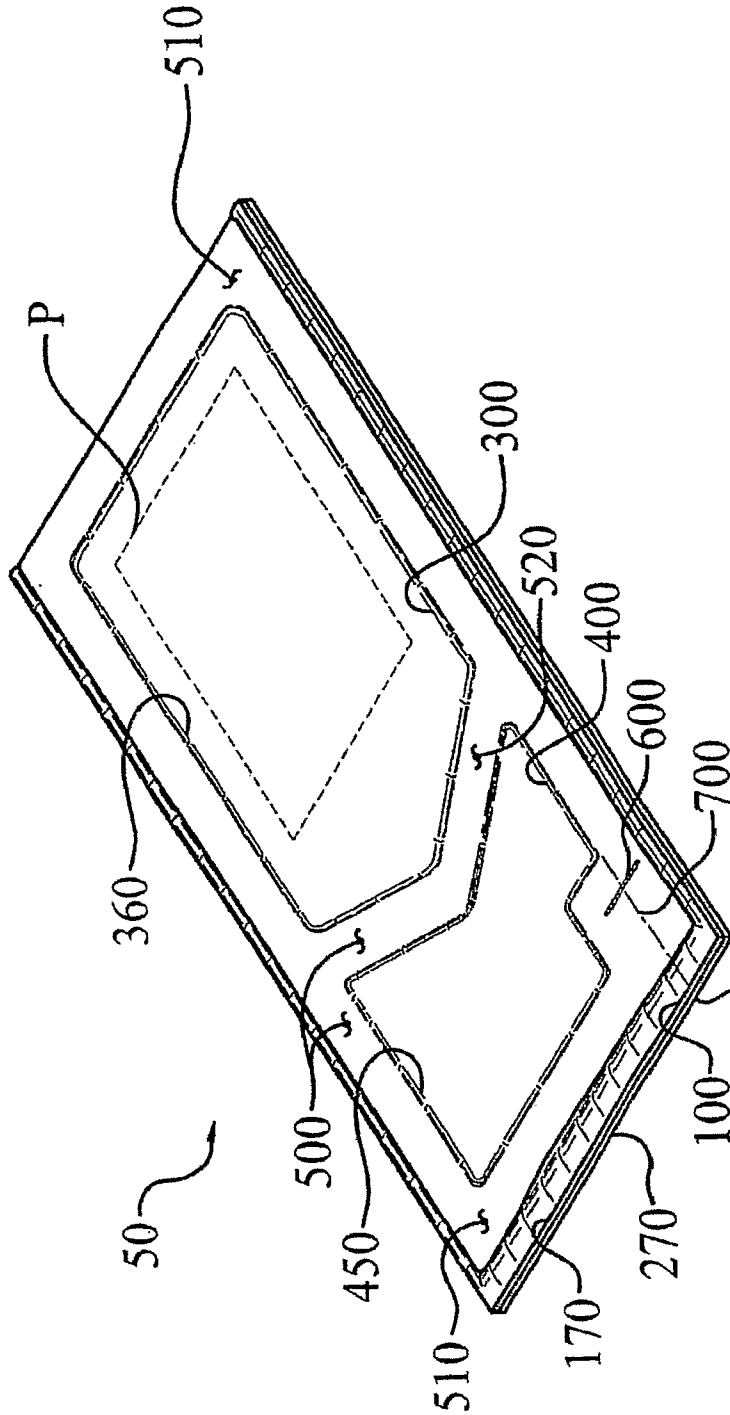


Fig. 1

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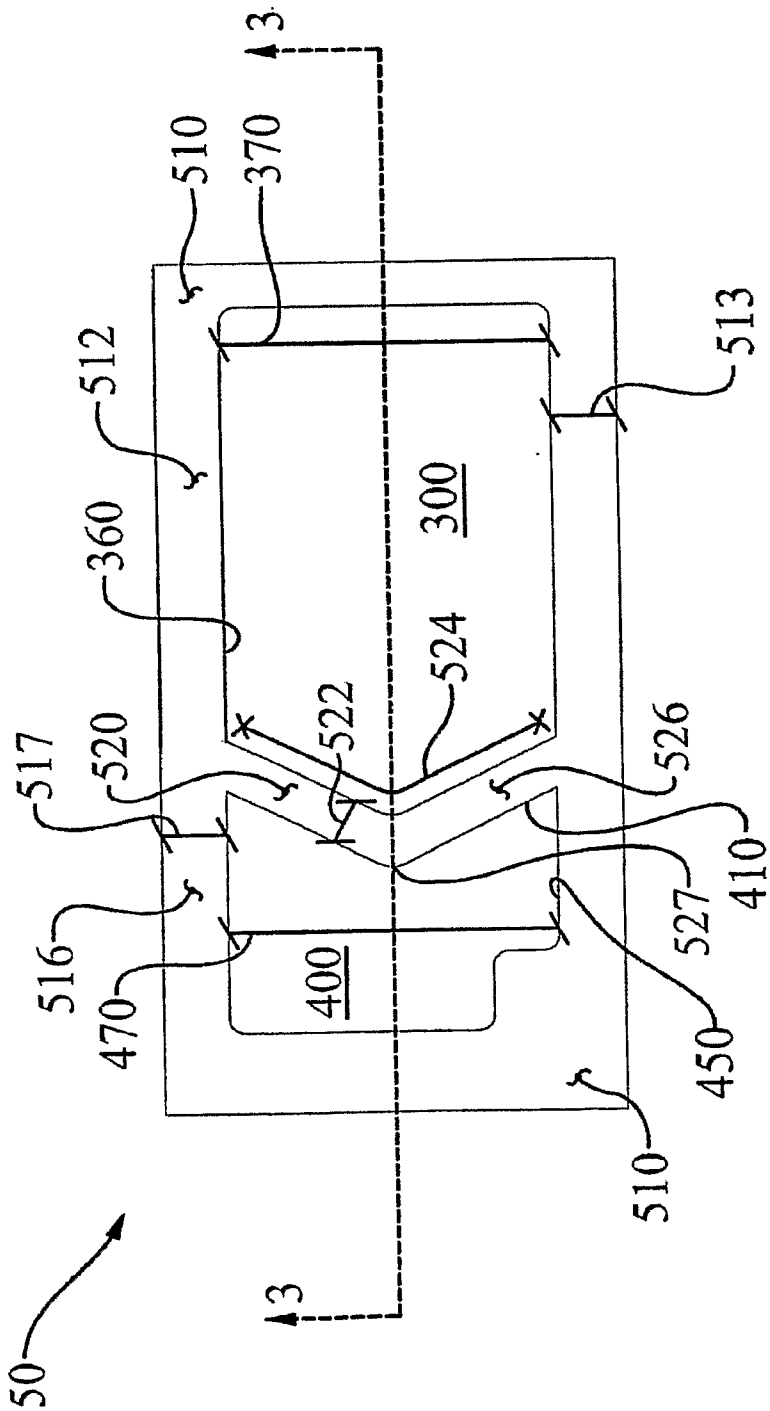


Fig. 2

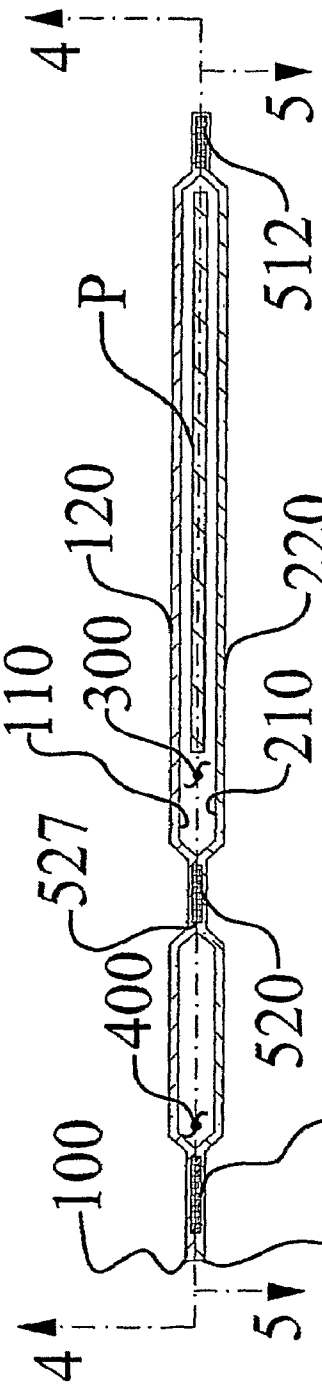


Fig. 3

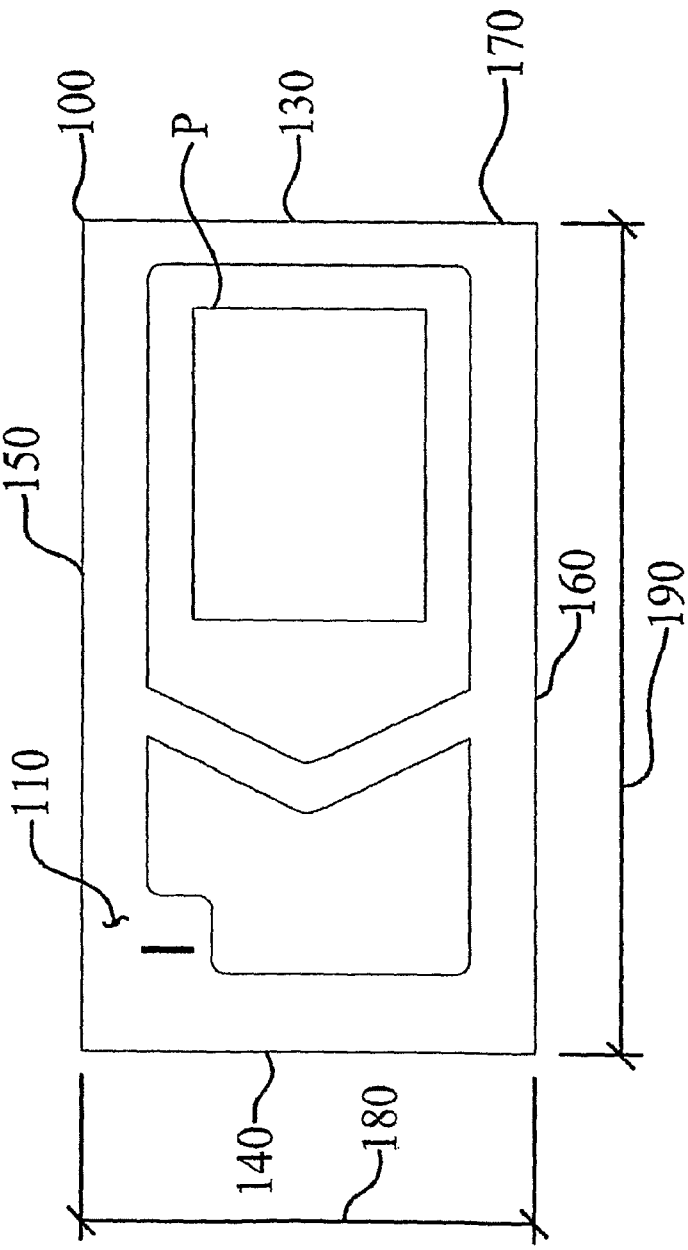


Fig. 4

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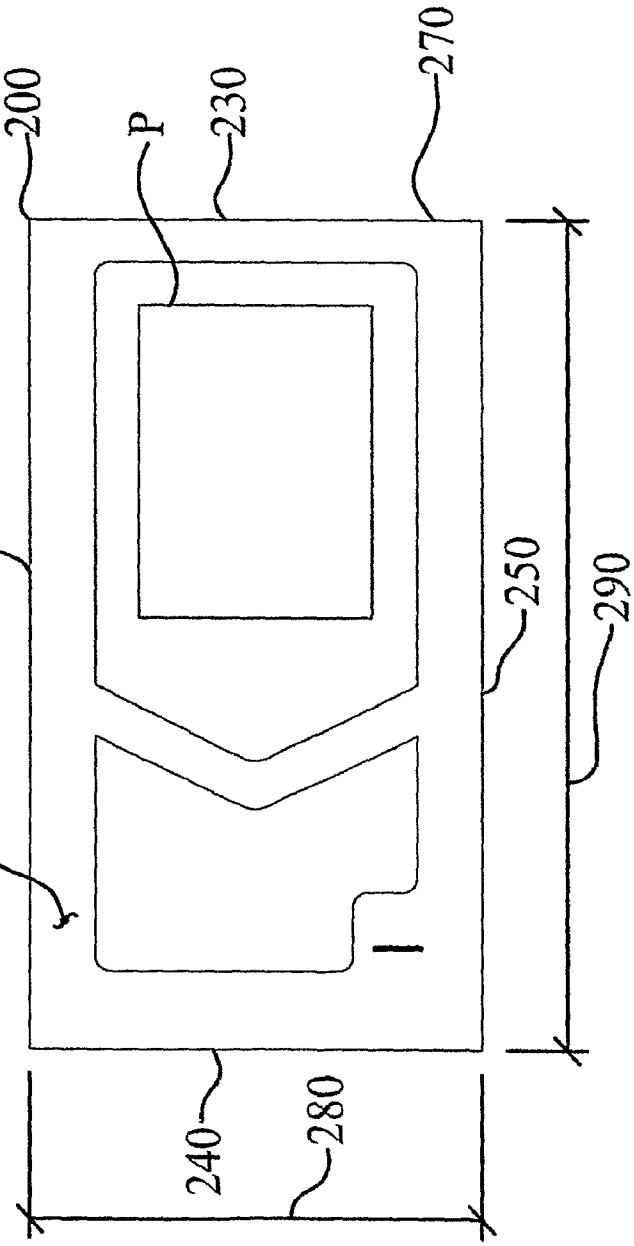


Fig. 5

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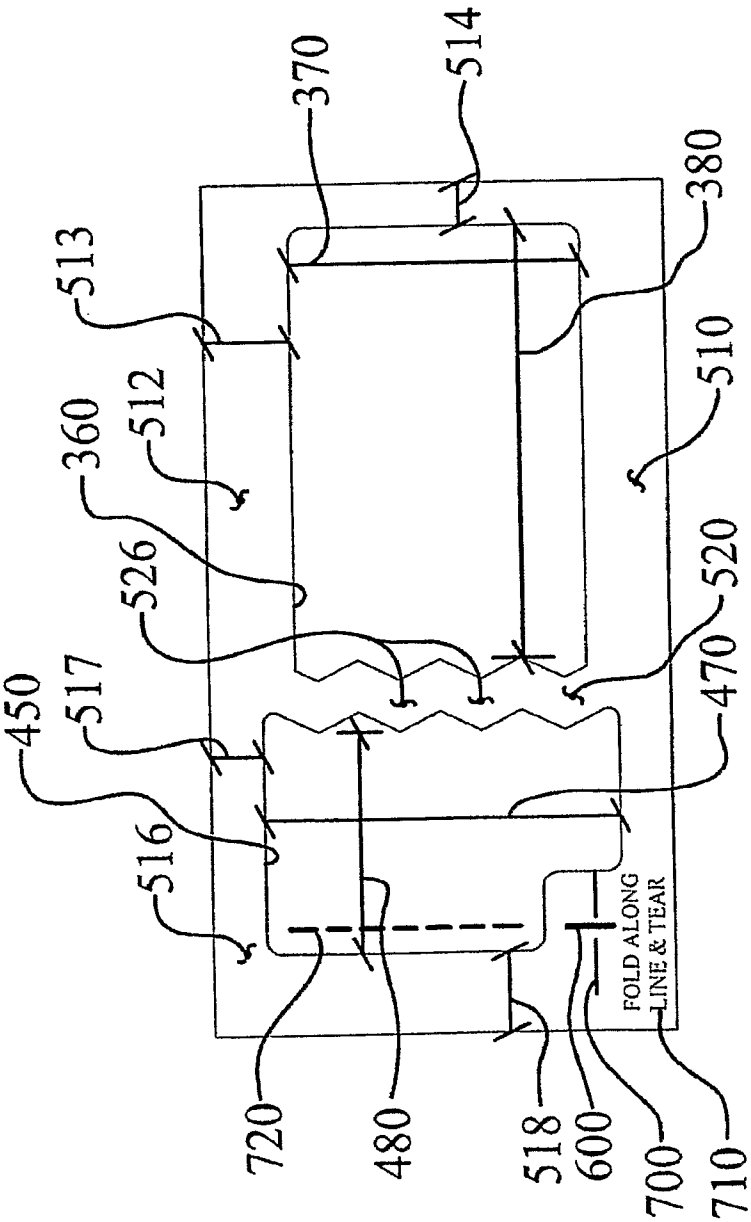


Fig. 6

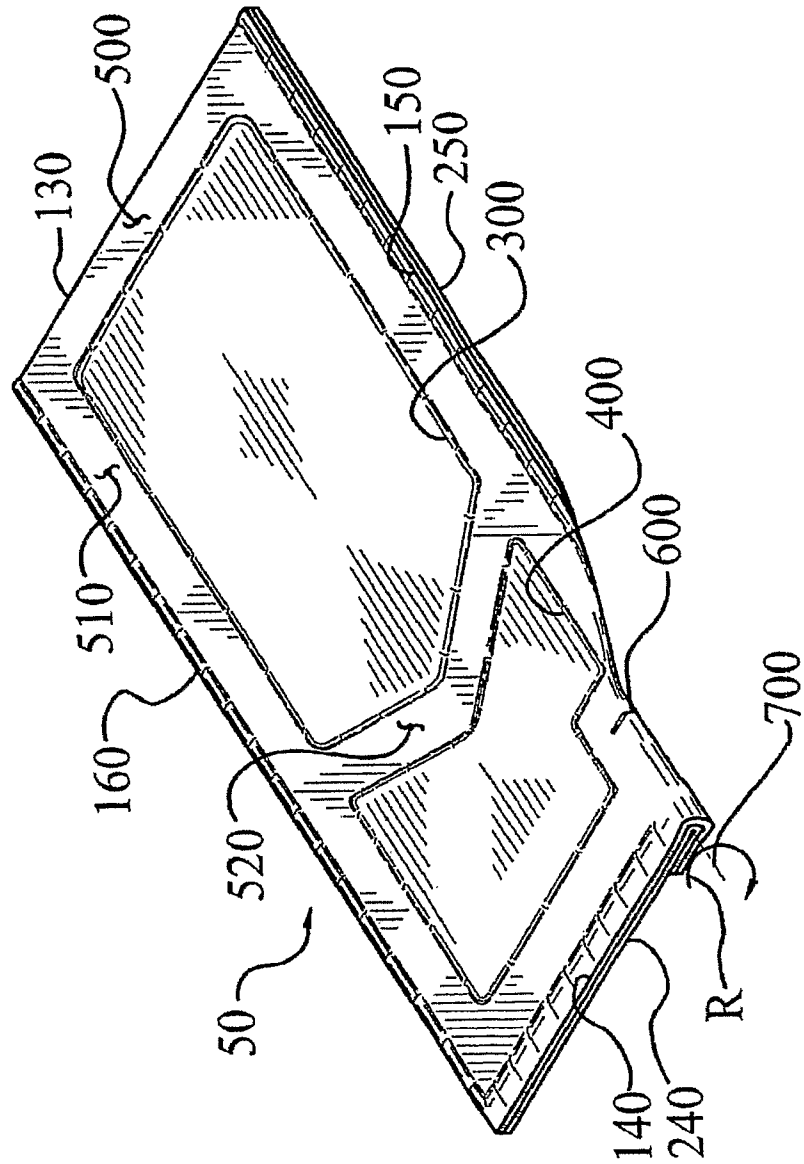


Fig. 7

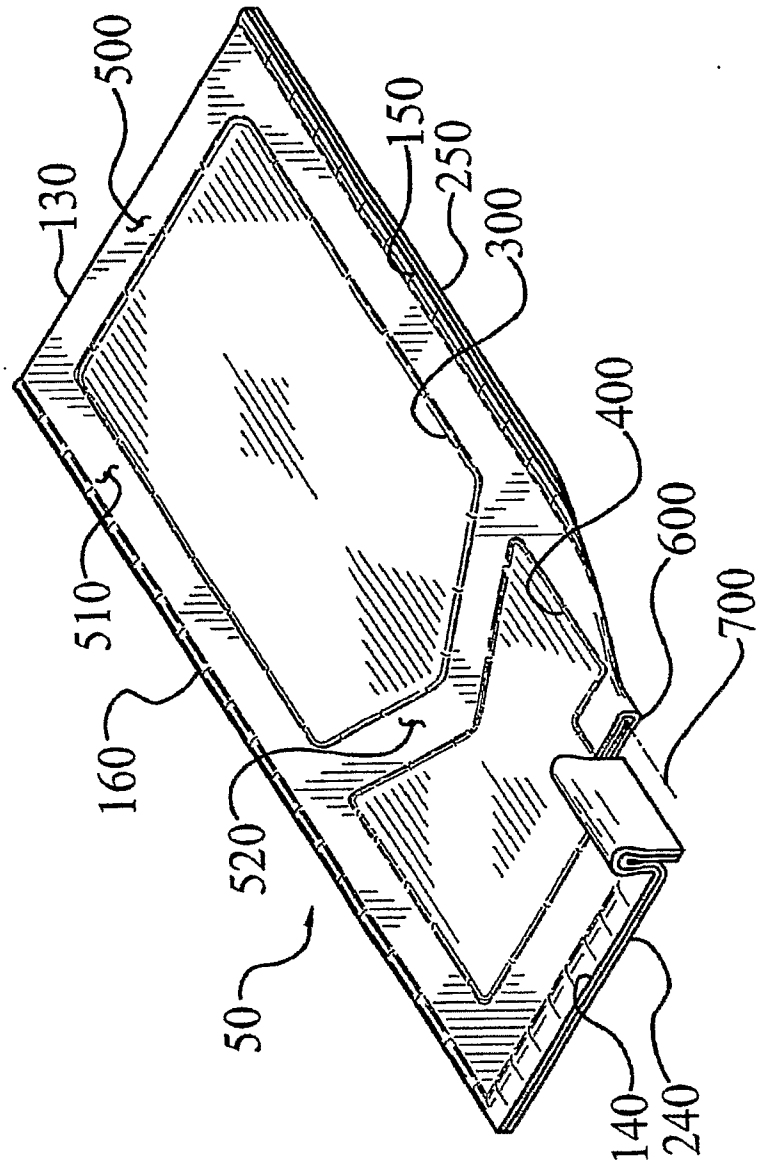


Fig. 8

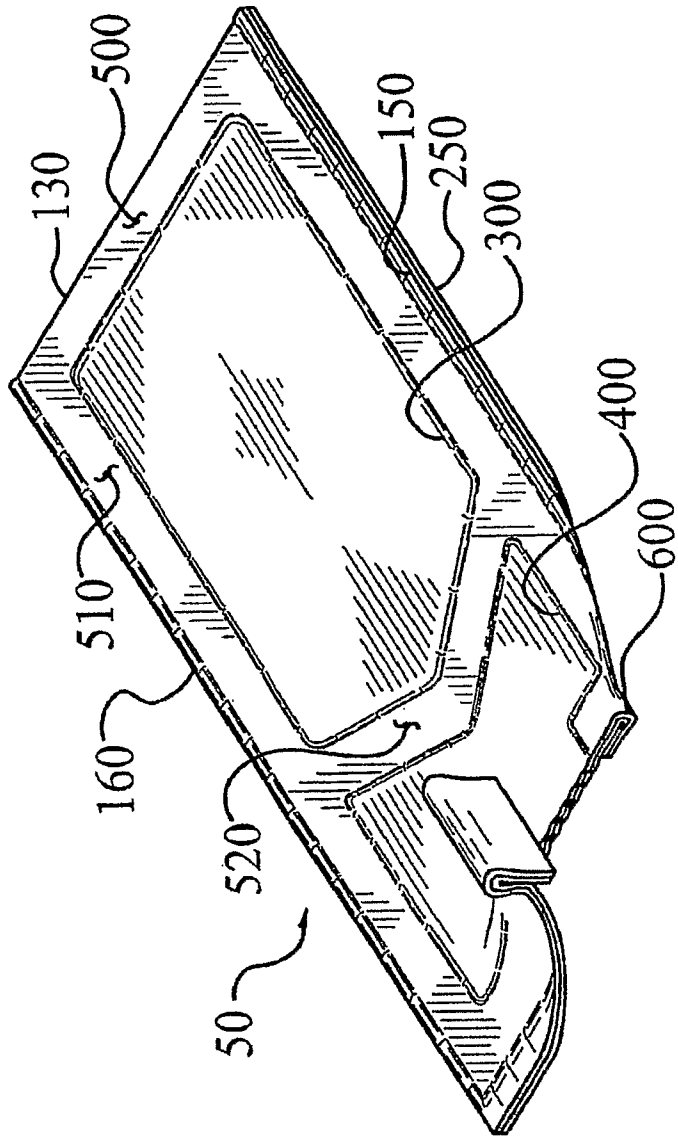


Fig. 9

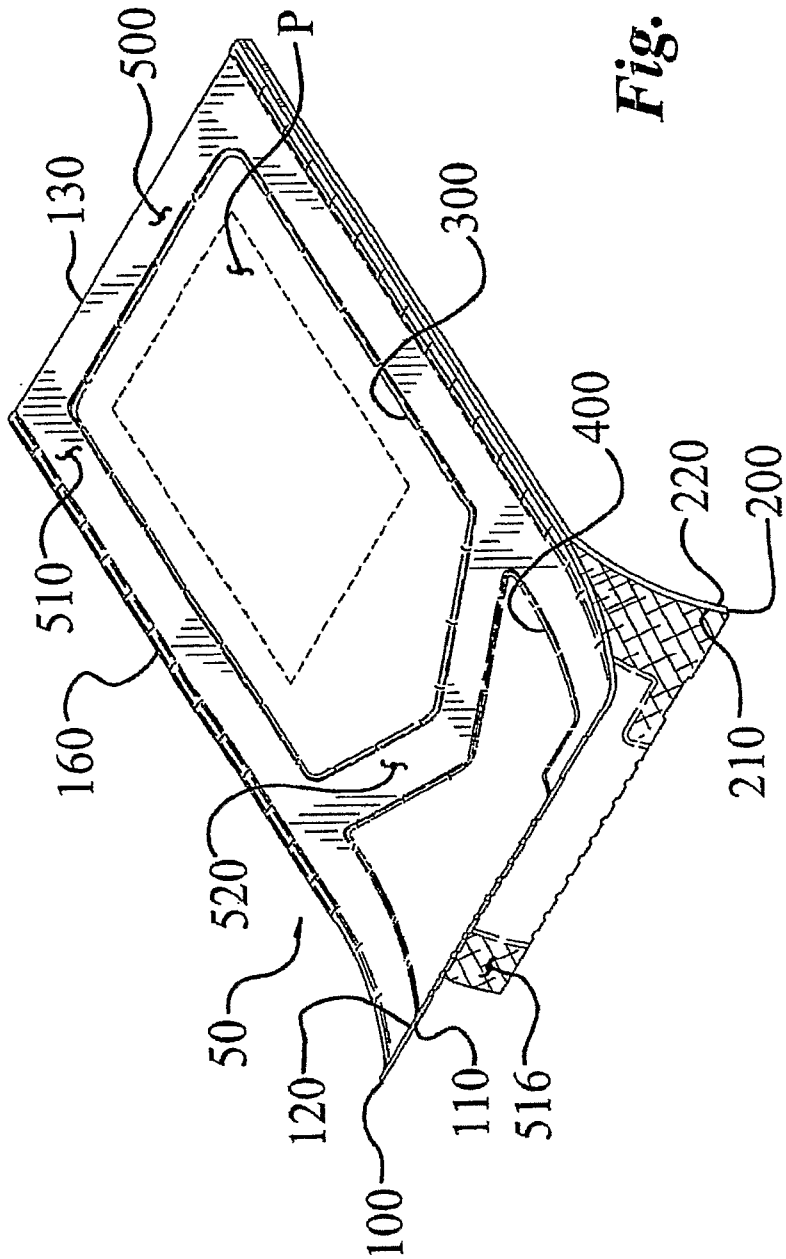


Fig. 10

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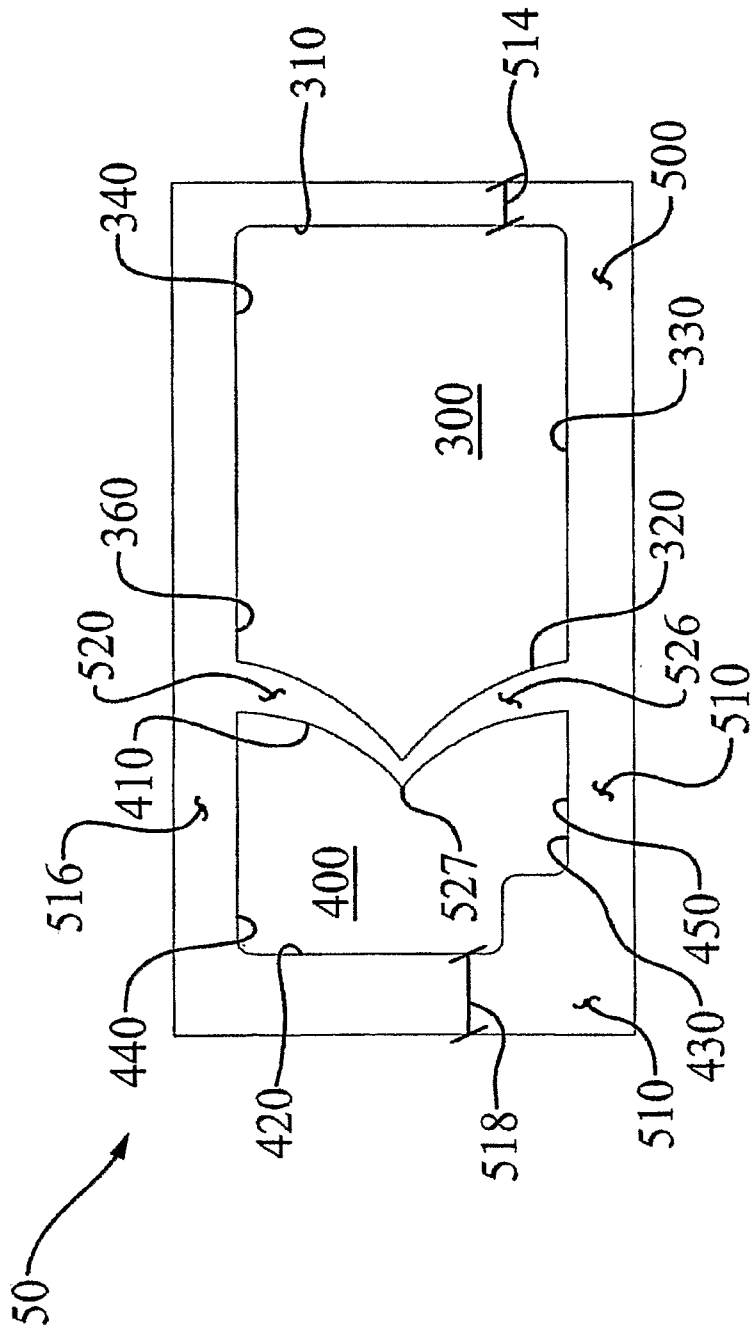


Fig. 11