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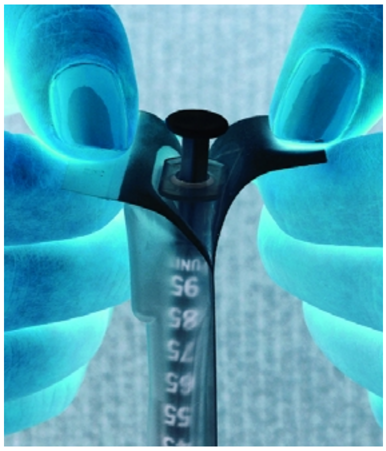
DuPont Tyvek®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Easy-Opening Packaging Systems

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Consistent peel strength without fibre tear has been a difficult property to obtain. This article discusses a range of peel options and compares the seals formed between different materials and a new grade of packaging material.

Open to innovation

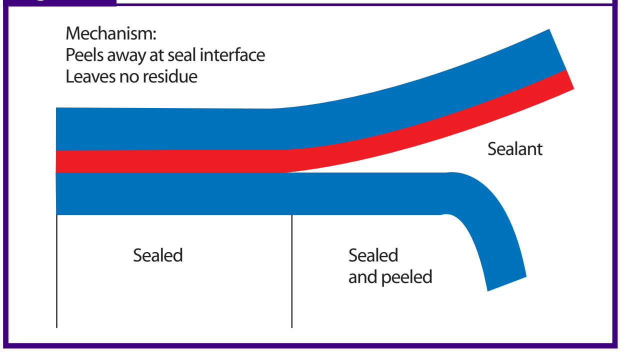
The market for medical devices and related packaging concepts varies in the different global regions. For example, in North America it is estimated that 70% of gowns and drapes are single use, whereas in Europe reusable gowns and drapes are traditionally used. However, the current estimated market share of 30% in Europe for single-use gowns and drapes is growing. This trend is generating new opportunities for innovative packaging applications, despite the supply chain facing tremendous cost pressure because of consolidation of purchasing groups.

Running converting equipment at higher line speeds, and the use of cast-film equipment rather than conversion techniques such as blown film as well as more layers in the film have been introduced to achieve lower costs. However, the medical device industry is more conservative to adopting changes than, for example, the food industry, because of the greater need for certification and revalidation. This article focusses on easy-opening applications and meeting the demands for a clean peel, whereby on opening no particles of material are emitted at the interface of the seal. More than 90% of packaging is dominated by four peel concepts that can lead to a clean peel. These concepts are discussed below.

Interfacial peel

In this concept, the peel takes place between the seal layer (a peelable compound or sealant) and the substrate such as a polypropylene-based tray (Figure 1). The mechanism is based on polar or electrical interactions that lead to a clean and fibre-free peel because no diffusion takes place between the polymers. The peelable compound is based on ethylene-vinylacetate (EVA) or ethylene-methylacrylate (EMA), which provide a versatile peel to substrates such as polypropylene (PP), polystyrene (PS), polyester (PET), poly(vinyl chloride) and flash-spun high density polyethylene (HDPE) (Tyvek®) (Figure 2). Peel strength (delamination values) is mainly controlled by the composition of the compound and the thickness of the peel layer; a thinner seal layer leads to lower peel values. Moreover, the general theory of adhesion can be applied, that is, a softer and more elastic structure/peel layer generates higher delamination forces.

Figure 1: Adhesive failure of the sealant.



Cohesive failure peel

The most commonly used peel concept is based on a cohesive failure of the sealant (Figure 3). This effect is achieved by blending a second, incompatible component such as polybutene or polar ethylene-copolymers to the sealant layer, which is constructed from polyethylene (PE), EVA or ionomer. The mechanism is →

Figure 2: Peel performance of an EMA-based concept.

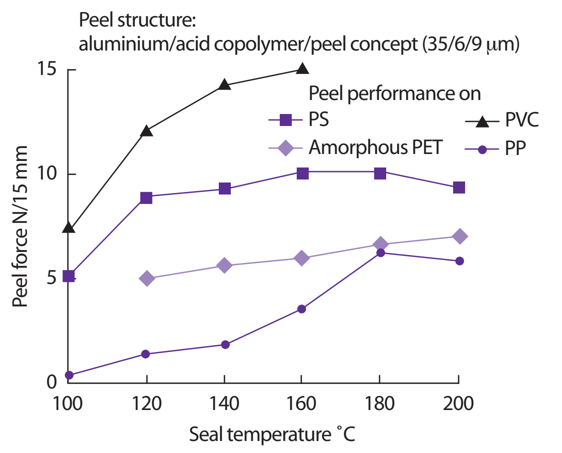


Figure 3: Cohesive failure of the sealant.

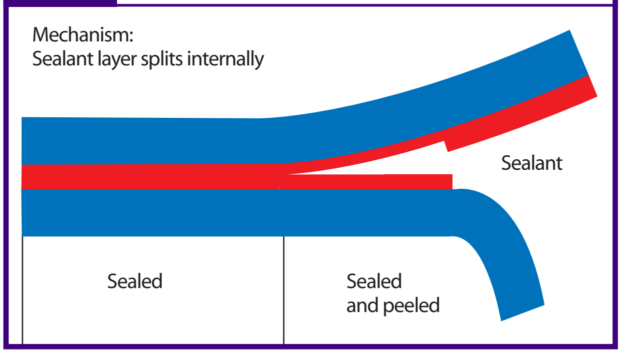
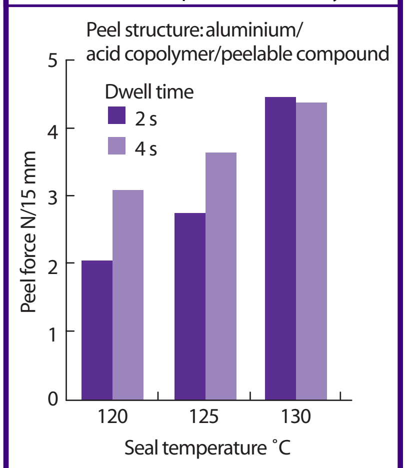


Figure 4: Peel performance of an EMA-based concept on uncoated Tyvek.



diffusion between the polymers followed by a mechanical failure in the sealant. It is critical to control the mechanical and rheological properties of all materials involved to avoid undesired fibre tear. This involves manipulation of the mechanical properties such as tear propagation (easy-peel properties) and fine tuning the rheological properties of the polymers such as viscosity or flow behaviour.

Burst peel/Delamination peel

In this concept, the sealant delaminates from the next layer in the structure. A well-known example is a burst peel in which a thin ionomer layer seals to itself and delaminates from an HDPE layer. This can be achieved in simple two-layer structures as well as in multilayer structures, which can be crystal clear and have barrier functionality as an option. Barrier functionality can be achieved by coextrusion with typical barrier layers such as ethylene vinylalcohol (EVOH) or polyamide (PA). An example of this type of structure would be PE/tie layer/10 µm of EVOH/10 µm of HDPE-based tie layer/7 µm ionomer.

Continuation peel

For this concept, low tear propagation, that is, easy-tear properties are needed in the material and, in addition, the package needs to have a notch or a perforation to start the easy-opening process. Typical examples are sachets used for pharmaceuticals and personal care products, and bags made of plastic film used to pack gowns. For sachets, the main part of the structure is generally aluminium (laminated or coextrusion coated), which is combined with zinc-based ionomers. Easy-tear plastic films require a thin, central layer of ionomer combined with PE, EVA or ethylene-acrylate copolymers.

An alternative continuation peel

Tyvek® is formed by randomly distributed, continuous, fine fibres of HDPE. These fibres are first flash-spun in a proprietary process in which HDPE is dissolved in a medium under temperature and pressure. Continuous strong, fine fibres form when the spin medium flashes off to gases at normal atmospheric pressure. Those fibres are then laid as a web on a moving bed before being bonded together by heat and pressure, without the use of binders or fillers. By varying the lay-down speed and the bonding conditions, the flash-spun sheet can be used for soft protective garments, hard structure envelopes or packaging.

When used as an alternative to coated paper or direct-seal paper, the most recent Tyvek® grade recommended for form-fill-seal applications offers 30% cost savings compared with traditional grades because the coating step can be omitted. The concept requires the forming (bottom) web to provide the seal and peel functionality. Typical structures would be PE/tie layer/ionomer/tie layer/peel layer or PA/tie layer/peel layer. The tie layer is a compound of different polymers that have the same chemical base as those in the peel or seal layer. Instead of the cohesive failure peel concept on a base of PE and polybutene blends, an EMA-based peel concept provides a clean, fibre-free interfacial peel to flash-spun HDPE (Figure 4). The structure here is PA6/tie layer/EMA-based peel concept.

This system provides the delamination forces of 4.5– 9 N/25 mm often needed in the medical industry. The first challenge is to consistently achieve fibre-free performance and a second challenge is to achieve "deep" draw packages on thermoform form-fill-seal equipment for large products measuring 25 mm to 150 mm. →

Applications

This system offers opportunities for packaging larger, less expensive medical devices, which are terminally sterilised by ethylene oxide, with a flash-spun top web. Gowns and drapes are packaged in gas-tight structures that allow no exchange of air or other gases beyond the normal diffusion that takes place through the polymer. A polymer-based tear propagation peel using a PE/ionomer/PE structure is widely used in flexible packaging. The key advantage of this design is that the pack can be easily opened without compromising sterility.

In addition to primary packaging, the tear-propagation peel of the system offers safety advantages for transport packaging. Rigid small- and medium-sized packs and containers are often bundled together with a shrink film on a polyolefine base. This tough, low-cost design can be opened with scissors or knives, which risks damaging the primary packaging. However, a study by PIRA <www.piranet.com> suggests that a substantial number of employees are injured by opening shrink film in this way. This can be overcome by a shrink film that incorporates a continuation peel.

Outlook

Reducing cost and retaining the high standards needed in medical applications is a challenge for the coming years. The innovations in the packaging industry such as increased automation of packaging machines together with more contract packaging of procedure sets can be used to upgrade well-established concepts for packaging and handling terminally sterilised medical devices. The potential cost savings in automation and improved performance should compensate for the time consuming revalidation procedures. mdt

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DUPONT

Tyvek®

Tough, protective materials for medical packaging

Tyvek® vs Medical Grade Papers

Tyvek® is a sheet of spunbonded high-density polyethylene (HDPE) which provides a unique combination of physical properties that no other sterile packaging material can match and whose coated and uncoated styles 1059B, 1073B and 4058B (2FS™) offer since more than 30 years: →

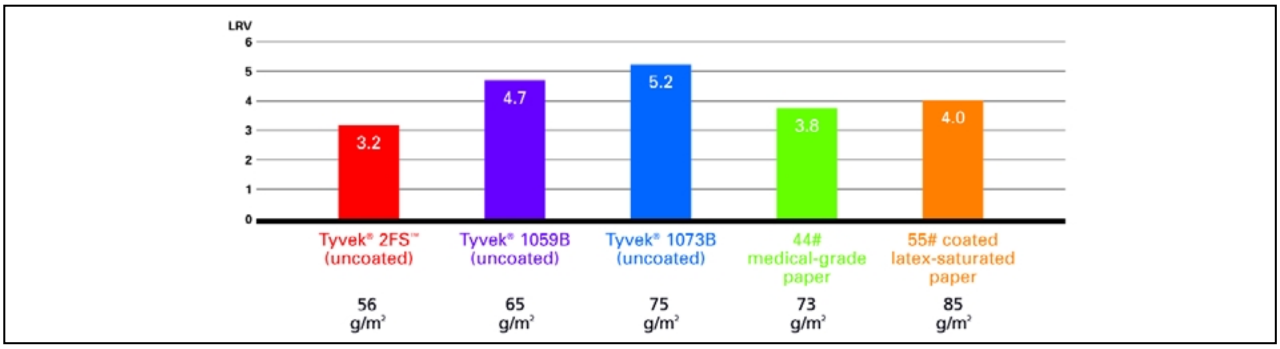

Figure A. Microbial Barrier Test Results: Per ASTM F1608. Microbial barrier is the measure of the ablility of a porous substrate to prevent bacteria penetration. Completely impermeable control sample (microbial penetration is zero) is challenged with one million or 10^6 coony forming unity (cfu). The number of cfu 10^6 has a $\log_{10}$ value of 6. If a sample challenged in the same way as the control allows 10 cfu (log 10 =1) to penetrate, then its log reduction value (LRV) is 5 (6-1=5). Therefore, the higher the LRV, the more resistant the packaging is to bacteria and microorganisms.

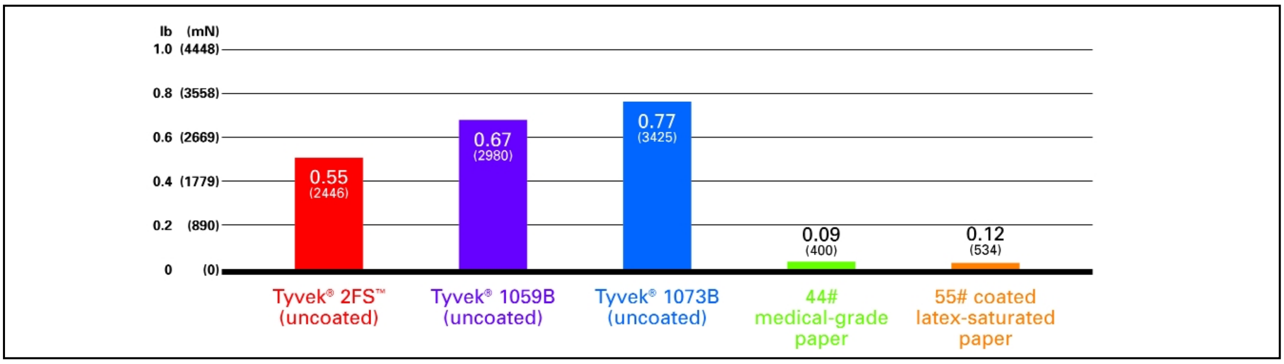

Figure B. Elmendorf Tear (MD) Test Results: Per ASTM D1424 and DIN EN 21974. Ekmendorf Tear measures the force required to propagate an initiated tear from a cut or a nick. MD signifies machine direction. The higher the value, the less likely a material will tear under force.

➔ **• excellent microbial barrier resistance**

Even under the most rigorous conditions of high stress, Tyvek® maintains sterility from the point of sterilization until a product reaches its end-use. Tyvek® is highly resistant to bacteria spores and other contaminating micro-organisms and outperforms other porous packaging materials, including medical-grade papers.

• superior tear strength and puncture resistance

Made of tough and continuous fibers, Tyvek® is up to 8 times stronger than medical-grade papers of equal or greater weight and protects package integrity from both product breakthrough inside and rough handling outside.

• clean peel

When opening a package, the risk of creating fiber tear or generating particulates in the operating theatre is unwelcome with medical-grade papers. This risk is greatly reduced by using coated or uncoated Tyvek® with an appropriate peelable bottom web. Particulate generation tests comparing Tyvek® to medical-grade papers prove that Tyvek® generates far fewer air-borne particulates that could contaminate a sterile environment and cause infection.

• exceptional resiliency

Tyvek® is an extremely flexible packaging material that won't break or tear as easily as medical-grade papers. Form/fill/seal packaging lines runs smoothly.

• outstanding water resistance

Thanks to its high resitance to penetration by water and other liquids, Tyvek® protects the integrity and sterility of packaged medical devices. Unlike medical-grade papers, Tyvek® maintains its strength both wet and dry.

• unmatched sterilization compatibility

Tyvek® is specially engineered to enable sterilizing gases and moisture vapor to penetrate and escape quickly, which makes it compatible with all commonly used sterilization techniques (EtO, gamma, E-beam, steam*) and emerging technologies (STERRAD® Sterilization System from Advanced Sterilization Products).

* under controlled conditions

DUPONT® Tyvek®

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