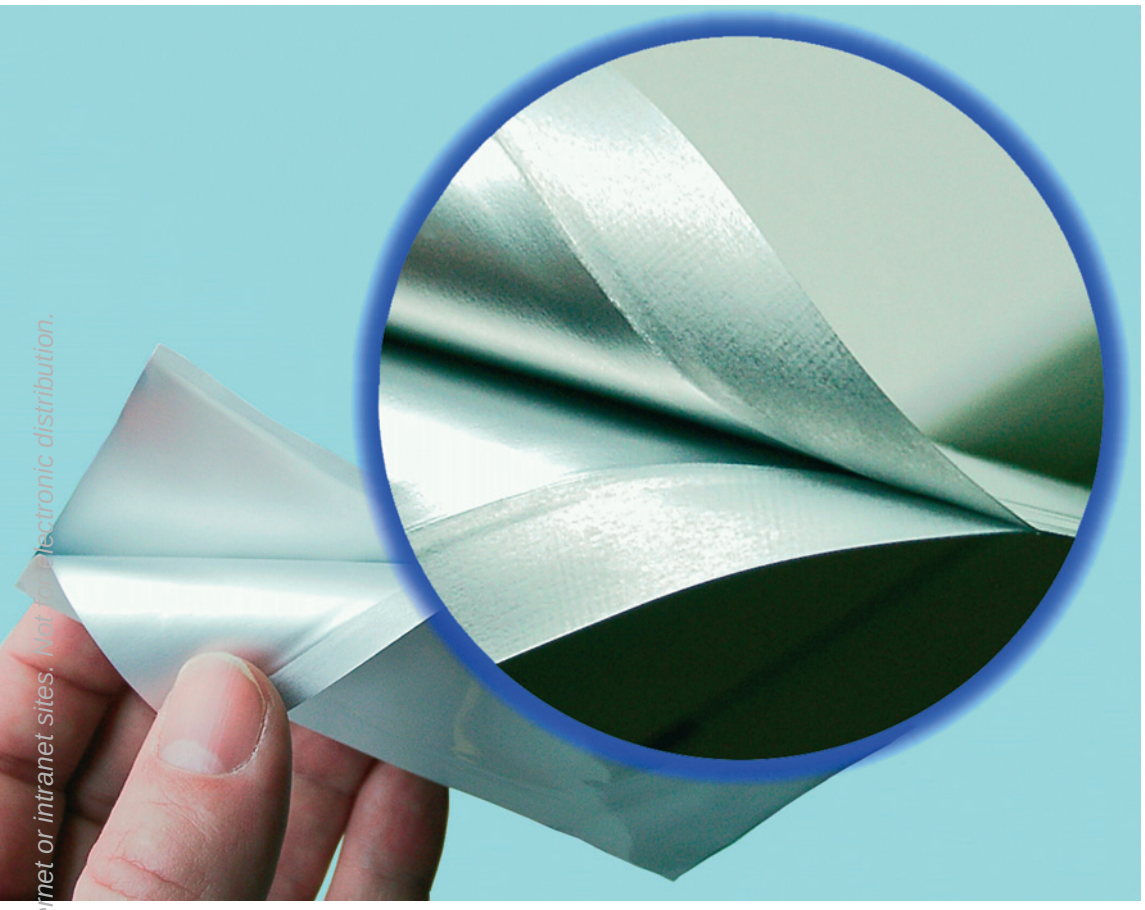

In the peel pouches used as sterile packaging for surgical instruments and medical equipment, polybutene-1 in the sealing layer permits fast, controlled opening of the packaging without the formation of "angel hair" that could contaminate sterile articles

Easy and Safe to Open

Packaging Surgical Instruments. Easy-open peel packaging has long proved successful for food products. Polybutene-1 (PB-1) is used as a component in the sealing layer. From newly developed films containing PB-1, practical peel pouches for surgical instruments and equipment can now also be produced.

PETER STOBER
HARRY RIST

In the operating theatre, speed is of major importance during an operation – and that is also valid when opening protective packaging for surgical instruments, catheters or prostheses. The usual packaging for surgical instruments and equipment is however tightly sealed and often difficult to open without some type of aid. With this problem in mind, EK-Pack Folien GmbH, Ermengerst/Germany, decided to develop a film for its customers in the medical sector that would permit fast, controlled, angel hair free opening of packaging, even with gloves on – as is required in operations.

Successfully Proven for Food Packaging

For many years now, EK-Pack has been producing co-extruded peel films for easy-opening food packaging (Fig. 1). In these films, polyethylene (PE) and PB-1 are used for the sealing layer. The peel effect depends on the controlled "incompatibility" of these two materials. In the melt and during crystallisation, separation takes place. Many small PB-1 islands are formed and finely dispersed in the matrix material throughout the total thickness of the peel layer (Fig. 2) without influencing optical properties of the film significantly. At the contact points ▶

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between these islands and the matrix material, adhesion is rather weak, thus, that built-in tear points are formed. During the opening of the pack, the tear propagates within the sealing layer from one PB-1 island to the next (Fig. 3). In this way, the packaging can be opened easily with constant force.

Peel Force Adjustable to Customer Requirements

The initial and tear propagation force can be adjusted to customer requirements by varying the quantity and degree of dispersion of PB-1 and choosing appropriate PE grades for the matrix material. Peel forces ranging from 1 to 10 N (measured on 15 mm-wide strips) can be achieved with suitably close tolerances. Typical values lie between 4 and 6 N/15 mm with PB-1 contents of 12 to 20 wt.-% in the sealing layer.

Fig. 1. Peel films for easy-open food packaging

These films containing PB-1 can be processed without any problem on conventional packaging machines. The sealing temperature range is exceptionally wide, generally between 120 and 180 °C. Another advantage of this packaging is the distinct white fracture behaviour (tamper evidence) of the seal, which serves as a simple but effective quality characteristic. It enables packagers to verify that the packaging has been perfectly sealed. At the same time, consumers can see instantly if the original seal is still intact or if someone has tried to open it.

Modified for Fast Opening

EK-Pack now had the idea of offering this packaging concept to its customers in the medical sector as well. The company first investigated whether the film formulation used for food packaging was also suitable for packaging surgical instruments and medical equipment. It was found that, especially when the packaging was opened rapidly, very fine filaments (angel hair) were produced at the interface, which could contaminate sterile instruments or equipment. EK-Pack therefore had to modify the formulation.

EK-Pack referred this problem to Ultrapolymers Deutschland GmbH, the distributors of PB-1 for Basell in Germany, Austria and Switzerland. Together, EK-Pack and Ultrapolymers tested the possibilities for adapting the film formulation to the desired requirements. The choice was finally narrowed down to three different formulations that varied in terms of PE grade and PB-1 concentration. EK-Pack subjected the films produced with these formulations to comprehensive laboratory tests.

Tested in the Laboratory ...

The films were first sealed in the laboratory under defined conditions in order to determine seal strength and peel force. At the same time, by manually opening the sealed films – both rapidly and slowly – EK-Pack gained initial subjective impressions of tear behaviour and "angel hair" formation (title picture). Cross sections of the torn seals (so-called microtome sections) were then examined under a microscope to investigate at what points the film had torn, how the tear had propagated and how the PB-1 was dispersed in the sealing layer.

On the basis of the test results, EK-Pack determined the film formulation in which the sealing layer with PB-1 and the supporting layer were optimally harmonised. In this formulation, the PB-1 is very finely and uniformly dispersed in the sealing layer and does not migrate into the supporting layer, even during sealing, because this would encourage the formation of undesirable "angel hair".

Opening mechanism

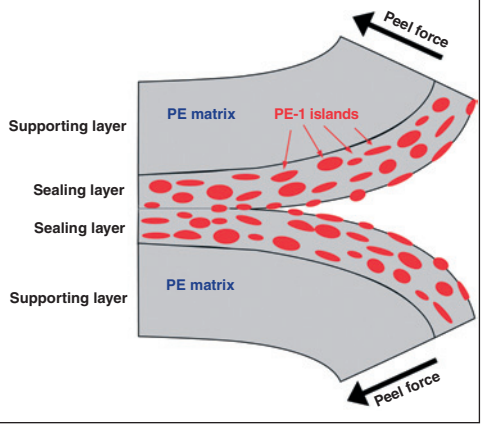

Fig. 3. During the opening of the pack, the tear propagates within the sealing layer from one PB-1 island to the next. In this way, the packaging can be opened easily with constant force

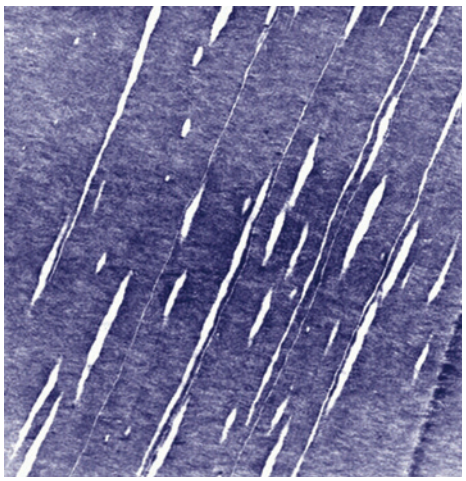

Fig. 2. Photomicrograph of the PB-1 islands in the PE matrix

In Profile: EK-Pack

EK-Pack Folien GmbH, a medium-sized private company with registered office in Ermengerst (near Kempten/Germany), has been developing and producing flexible packaging film (Fig. 4) for more than 25 years. The company employees nearly 200 people and achieves annual sales of more than EUR 50 million. All processes at EK-Pack are certified under DIN EN ISO 9001:2000 and the hygiene standards BRC/IoP (UK) and HACCP (Hazard Analysis and Critical Control Point).

The packaging films produced are multilayer flat and blown films with up to 14 layers – unprinted or printed (8 colours flexographic printing), optionally extrusion laminated and/or coated, alternatively laminated without the use of solvents. The materials used for production of these films are PA, PE-LD, PE-LLD, mPE and EVOH; in addition supporting layers made from OPA, PET, paper, aluminium and OPP are employed. These films, which in some cases are specially tailored to customer requirements, are used in the food industry as well as for pharmaceutical, medical and industrial applications.

Fig. 4. Extrusion of peel films containing PB-1 at EK-Pack. (From left to right: Peter Stober from EK-Pack, Harry Rist from Ultrapolymers Deutschland GmbH, Rupert Sailer from EK-Pack)

... and Passed the Practical Test

Tests carried out under practical conditions by a manufacturer of pouches for surgical instruments and medical equipment confirmed the good suitability of the film formulation. The films could be sealed without any problem on existing packaging lines and the packaging tore solely along the sealing layer without the formation of "angel hair" – even at high tear rates. Sterilisation of the pouches by gamma radiation or hydrogen peroxide also caused no problems.

EK-Pack markets these films under the trade name MediPeel. These are coextruded films with PE as the supporting layer and PE/PB-1 as the sealing layer. The total film thickness ranges between 50 and 100 µm, depending on the application. The films are laminated in-house to diverse materials such as PET and OPA films or aluminium foils by solventless lamination or extrusion lamination. In the example shown, the film has the following structure: PET 12 µm/aluminum 8 µm/PE 50 µm. It is used to produce pouches in various sizes for surgical forceps, scalpels, catheters, implants and other sterile articles.

At present, EK-Pack produces 50 to 100 t peel film per year. In view of the strong demand in the medical sector, the company expects rapid sales growth for these specialties. ■

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