A Brief History of the Blister Pack

The appeal of the blister pack continues unabated – and is likely to do so for many years to come.

By Bernd Webel at Romaco

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For well over four decades, the blister pack has offered a cost-effective and practical method of delivering unit dose packaging. It has proved to be one of the most enduring, versatile and adaptable pack forms, and its popularity has continued to rise unabated in the European market, sometimes assisted – and at other times potentially threatened – by changes in the regulatory environment.

A child of the sixties, the pharmaceutical blister was conceived initially as an aid to patient compliance; this acquired particular significance with the introduction of the oral contraceptive pill. None of the other pack forms available at the time – which included boxes, metal or glass tubes, glass bottles and strip packs – lent itself easily to the task.

Once established as the pack form of choice for oral contraceptives, the blister pack's advantages and potential for wider use became rapidly apparent. In addition to improved patient compliance, the blister also offered convenience, tamper evidence and a high degree of product protection and stability, particularly for hygroscopic or friable tablets. Benefits for the manufacturer included generally lower production and storage costs than for bottled tablets, and improved opportunity for the inclusion of essential patient information, as well as branding.

Figure 1: Advantages of the pharmaceutical blister include improved patient compliance, convenience, product protection and low production costs

BLISTER MACHINES

Machine manufacturers rose quickly to the challenge of meeting this demand, with a coterie of German producers taking the lead, soon to be followed by the Italians. These two nations are still the leading producers of blister machines. The early machines established principles of operation, some of which are still in evidence today: the very first machine, for example, operated on the intermittent motion principle for forming, sealing, perforating and cutting – as do many modern machines.

While the fundamental principles of operation have remained largely unchanged, the latest machines are highly evolved creatures compared with their ancestors. Developments over the years have increased output, facilitated the integration of blister machines into complete packaging lines, widened the scope of application to enable packaging of a wide range of products and allowed the accommodation of different substrates.

The first interconnection of a blister packer and cartoner occurred in the mid-sixties, while the first fully integrated, compact line made its debut just a decade later. These early mechanical solutions were the forebears of the hi-tech plc and computerised options now available, which allow fully automatic operation from product-loading right through to palletisation.

ORIGINAL PACK DISPENSING

The 1980s was perhaps the fastest period of growth in demand for blister-packed products in Europe, as governments across the continent began to advocate original pack dispensing (OPD) as the preferred means of delivering products to patients. The key benefit of OPD was that the risk of product tampering, contamination or dispensing errors was largely eliminated, since the product is delivered to the customer exactly as it leaves the packaging line, as opposed to the traditional method of pharmacists dispensing the required amount of medication from bulk supplies. In response to this market trend, machine manufacturers began to offer increased outputs: in the early 1980s 420 blisters/minute was considered high speed, by the end of the decade this had doubled, and today outputs of 1,200 blisters/minute are not unknown.

A second effect of OPD was the increased responsibility borne by manufacturers with respect to product and packaging security: the elimination of pharmacy dispensing reduced the risk of dispensing errors, but conversely it also removed the final line of control before a medication

reached the patient. Visual inspection by operators was one possibility but, with production speeds increasing, this was seen as inefficient compared with 100% electronic inspection by camera or sensor. Machines therefore needed to be capable of reliably hosting these inspection devices.

Table 1: Specifications for push-through and peel-push blisters

Push-through	
Base web	*Lidding material*
PVC 250µm	Alu 25µm, soft – with/without perforation
PVC 250µm	Alu 30µm, hard – special embossing
PVC 250µm	Alu 9µm, soft/ paper 50gsm
PVC 250µm	Alu 9µm, soft/ Pergamin paper 35gsm
PP 300µm, white opaque	Alu 7µm, soft/paper 40gsm
PP 300µm, white opaque	Alu 7µm, soft/paper 50gsm
PP 300µm, white opaque	Alu 7µm, soft/paper 50gsm
Peel-push	
Base web	*Lidding material*
Aclar 51µm/PVC 250µm	Paper 50µm / Alu 9µm / PVC 7µm*
PP 60µm / Alu 60µm, soft	Alu 20µm, hard / PET 23µm / OPA 25µm*

* with cross-perforation

Figure 2: While the fundamental principles of blister packaging are largely unchanged, new technologies are used to great effect, such as in the development of this multi-function blister transfer system

BLISTER MATERIALS

The first blisters were formed from a base web of clear PVC to which aluminium lidding foil was sealed. While this combination is still used today for some products such as medicated sweets, most licensed pharmaceuticals are now packed in different combinations. The drivers for this have been two-fold: on the one hand, new materials offering a higher degree of product protection became available, and on the other, regulatory and legislative pressures have had and continue to have a significant impact on producers.

The significance of product protection varies according to the susceptibility of the product to moisture and the climate of the territory to which it will be supplied. PVC exhibits permeability over time and is therefore not suitable for sensitive products in the more humid regions of the world. Alternatives developed over the years include PVC/PVDC combinations, multi-layer and proprietary films, PET and PP, and – ultimately – the alu-alu blister. Most combinations are in use today, some requiring specially-modified forming stations: PP, for example, needs special handling due to its specific behavioural characteristics when heated, while care must be taken when forming aluminium to avoid stress points which could result in pinholes.

The greatest impact by far on the choice of materials has been created by ever-tighter regulatory controls, particularly with respect to child-resistant characteristics of blisters. This began in the US in 1970 with the Poison Prevention Packaging Act, which resulted in the production of many variations of the blister, including some that were extremely complex, both to produce and to open. As a result, only 20% of products in the US are packed in blisters and the vast majority of these are oral contraceptive pills, which are rarely – if ever – implicated in accidental poisoning.

Germany has had a DIN standard for pharmaceutical packs in place since 1979, which features more user-friendly solutions. These are based primarily on variations in the lidding material and the use of perforation. Specifications are available for both push-through and peel-push blisters (see Table 1), which appear to have achieved their aims, indicating that less extreme measures than those in the US are in order. Indeed, according to the Proprietary Association of Great Britain (PAGB), there has been no increase in the rate of accidental poisonings over the years, despite the increased use of strips and blisters.

A number of EU states are considering, or are in the process of introducing, legislation, and the EU will shortly introduce its own specifications for blisters, which will supersede existing legislation in all member states. In the meantime, producers must try to find a compromise solution for affected products which simultaneously assures child-resistance, does not compromise ease of access to blisters for the elderly, and has minimal impact on operating procedures and costs.

COSTS

As in every area of business, cost is a key factor. In many parts of the world life expectancy is increasing – a desirable state of affairs but one that inevitably places a strain on healthcare budgets. As a result, governments have put pressure on manufacturers to reduce the cost of medications – most publicly in the US in 1993 when, on the election of her husband as US President, Hillary Clinton pledged to tackle the issue head-on. The debate continues to this day and the past decade has brought some major changes in the way companies operate. The new business model has had considerable impact on the role of blister machines, and has broken down traditional pre-conceptions and boundaries in the industry.

The greatest change has been in the level of utilisation of resources. Traditionally the pharmaceutical sector justified a lower level of equipment utilisation than other industries because of the need to avoid cross-contamination of products: many lines were dedicated to specific products.

Figure 3: Fast changeover and easy cleaning are essential criteria for any modern blister machine: here an operator is able to remove and exchange a complete product feeding system in a matter of moments

Figure 4: Flexibility, reliability and ease of operation are demanded by the increasingly influential outsourcing community

Romaco's Noack 623 – seen here in action at UK contract house TD Packaging – fits the bill precisely and is generally regarded as the machine of choice for the sector

However, under pressure to reduce prices, manufacturers simply had to look to ways of cutting costs if profitability was to be maintained.

In this scenario, it is not feasible to have valuable production space and tools standing idle, awaiting the next batch of product. Increasingly, therefore, lines are used for different products, placing the issue of downtime for cleaning and changeover firmly in the spotlight. According to the old scheme of largely dedicated lines, the amount of time taken to change over a line was broadly irrelevant, since it was unlikely that the next batch would be required immediately. An additional complication is that batch sizes are generally diminishing, as purchasers adopt just-in-time strategies to reduce costs, and varying regulations in different markets impact on factors such as the number of products in a pack, and the amount and placement of market-specific information.

NEW PARADIGMS

As manufacturers increased utilisation, a number of new paradigms emerged. Foremost among these was that 'fastest' does not necessarily equal 'most productive'. We referred earlier to machines capable of producing up to 1,200 blisters/minute: these continue to be well-suited for the mass production of generic products, but where shorter batches are involved, the ratio of changeover to production time is completely out of balance. Increasingly therefore, producers need to consider their production profile – the number of batches and typical batch size – when specifying a machine. Start-to-finish batch times are the key here, and machinery manufacturers have worked hard to design machines which are easy to clean according to GMP regulations and which are fast to change over. Changeover times of less than 30 minutes are not uncommon now, thanks to the introduction of measures such as a reduced number of format parts, quick-release tooling and operator guidance via the machine's interface.

There is one section of the industry in which flexibility and fast changeover have always been vital and that is the outsourcing community. Traditionally, services such as packaging might have been outsourced for products perceived as being of lesser importance or lower value to the brand owner, or to supplement in-house packaging capabilities on an *ad hoc* basis. There will always be some demand for contingency operations such as this but the general trend now is for companies to outsource as part of a strategic plan. As the contract sector matures, growing both in volume and reputation, it is increasingly apparent that, in many instances, the decision to outsource provides access to facilities, expertise and cost-savings not readily available in-house. Outsourcing is now an 'added value' rather than a stop-gap service, and as a result the requirements of the sector – ease of operation, high flexibility, reliability for 24/7 operation and fast changeover – are increasingly being taken into consideration by machinery manufacturers.

Today blister machines fall into two broad categories, defined according to the method of sealing, which is either platen (the web remains flat as it is sealed by the pressure applied by top and bottom plates) or rotary (web is fed between two rollers). Traditionally, rotary sealing has been considered faster, while platen sealing offers a greater degree of flexibility, accommodating larger formats and non-standard products such as vials, which do not lend themselves to being fed between rollers. Again, the choice of method depends largely on production profiles, and the type and range of products to be packed. There are no significant differences in the quality of the seal – permeability and visual appearance – produced by the different systems which could materially affect any purchasing decision.

THE IDEAL BLISTER MACHINE

So what is the ideal blister machine for the current climate? Firstly, as we have demonstrated, the number of cases in which a high output is the governing factor is diminishing. Flexibility is generally more important, and potential purchasers should consider factors such as cleaning and changeover times, the ratio of machine footprint to output and ease of use. Additionally, there are a number of recent technological advances that can contribute to performance: these include XML technology – a new open standard which facilitates integration of ancillary and downstream equipment as well as daily operation – plus the wider use of servo technology to enhance a variety of functions. Add to this mix the magic ingredient of a supplier who can provide comprehensive support in areas such as training, validation support, planned maintenance and fast supply of format tooling, and your new machine could deliver many years of profitable service.

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