1|2011
White-Line – revolutionary concept for very small lots
Dear Customers,

The changes in the pharmaceutical market demand ever greater efficiency and flexibility, especially in the packaging process. Conventional machine optimisation and line optimisation techniques are no longer sufficient to offset the sometimes massive decline in productivity due to shrinking lot sizes. MediSeal’s LSC® – Late Stage Customization – concept already provides an opportunity to combine small packaging batches and then to customize them in a decoupled secondary packaging process, thereby increasing OEE by up to 25%.

With White-Line, MediSeal is further extending this concept to create a new, forward-looking packaging and logistics concept for lot sizes from 1 to 2000 blisters. In contrast to conventional approaches, the problem of very small lots is solved by further development of the production process and an optimised supply chain, providing a comprehensive Small Lot Solution. The modular system allows packaging of a pharmaceutical product in a single production process, without the time-consuming and expensive machine changes for specific national markets which would otherwise be necessary. This means that our customers can save a lot of time and money.

The ongoing social trend towards greater sustainability is placing ever more demands on packaging – the ecological footprint is now an important consideration for many companies when they develop and manufacture new products. The study carried out by our colleagues at Dividella shows how sustainability can be measured with regard to pharmaceutical packaging and that ecological and economic needs are not contradictory but actually complement each other.

The security of packaging also remains an important issue – tamper protection and tamper evidence are just two of the key concepts. With its innovative patented “folding box with Tamper Evidence”, Rondo has not only developed an effective means of protection but also keeps costs low and plant efficiency high.

I am especially pleased today to be able to introduce you to the SEIDENADER Group. Since the beginning of this year the companies, which specialise among other things in inspection machines and Track & Trace solutions, have been members of the KÖRBER MEDIPAK Group. This allows us to offer our customers an even broader range of services and an expanded presence in the markets, with new opportunities for cooperation. It only remains for me to wish you an enjoyable read!

My very best wishes,

Gerhard Breu

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Seidenader: enlargement and expansion for KÖRBER MEDIPAK

“We are overjoyed that we can expand our activities in the healthcare market of the future with Seidenader, an innovative company with some very exciting technologies.” This was how Richard Bauer, head of Körber, welcomed the new acquisition to the group at the end of last year. Today we would like to introduce the Seidenader Group and outline for you the possibilities of future cooperation with KÖRBER MEDIPAK.

With the acquisition of the Seidenader Group, which specialises in inspection solutions, KÖRBER MEDIPAK is significantly enhancing its expertise in the area of pharmaceutical packaging systems. The inspection and Track&Trace systems for the healthcare industry are an important and very promising addition to the range of services we provide.

Seidenader, based in Markt Schwaben near Munich, is a leading global manufacturer of inspection equipment, software and vision applications for pharmaceutical production. Vials, pre-filled syringes and ampoules are checked for product contamination, cosmetic defects and correct level. There is a wide range of models available, from a table top device for random sampling to a camera-based high-performance inspection machine with a throughput of up to 36,000 containers per hour. Both liquid and freeze-dried products are inspected. The range also includes exterior cleaning and drying machines, sorting and grading machines for tablets and syringes and ampoules are checked for product contamination, e.g. console systems, PLC programming and visualisation software. Finally, Seidenader Präzisionstechnik GmbH specialises in the production of precision mechanical parts and module assembly.

More than a century of innovation in the market

Seidenader have been developing machinery of outstanding quality for more than 115 years. This extraordinary wealth of experience enables the company to offer a full range of models to suit every requirement. A glance at the current Series VI in the high-performance inspection sector reveals some innovative elements for the parenteral products sector in terms of particle inspection and the detection of cosmetic defects such as scratches or cracks in the sidewall. The key factor is the modular design of the equipment, which enables customised machines to be designed to meet specific customer requirements. A new, patented system ensures transport at maximum speed with minimum product spacing. In this way, products are fed in, separated and then individually inspected. Production takes place in a new building which was expanded a few years ago to an area of 4500 square metres. In addition to its machine-building activities, Seidenader also specialises in business sectors which are directly related to the stringent quality requirements of the pharmaceutical industry: Seidenader Vision GmbH provides image processing solutions and customised inspection applications. Of particular importance in terms of quality and safety: the development of the company’s own Track&Trace systems enables product to be tracked to the patient and prevents not only counterfeiting of medicines but also confusion between products. Alongside Seidenader Automation GmbH as software developer, the group’s product range also includes programming and integration of software solutions, e.g. console systems, PLC programming and visualisation software. Finally, Seidenader Präzisionstechnik GmbH specialises in the production of precision mechanical parts and module assembly.

An ideal match: growing together

Seidenader and KÖRBER MEDIPAK complement each other perfectly: many additional joint development and growth opportunities will be generated in the future. Some of the Seidenader products complement the offerings available from our Dividella and MediSeal divisions – but many products are successful in the market quite independently,” says Gerhard Breu, KÖRBER MEDIPAK’s CEO. “The acquisition of Seidenader is part of our consistent commitment to our customers as a systems provider for integrated packaging solutions and technologies.”

In the past there have regularly been joint projects with MediSeal and Diviella, so the companies already know each other. This means that in the future customers will benefit even more from the transfer of know-how and the resulting innovative applications and integrated solutions for the pharmaceutical industry. At the same time, the KÖRBER MEDIPAK Group’s presence in world markets continues to grow.

Despite all the changes and the successful ongoing integration process, Seidenader remains an independent company; the existing corporate and management structure will remain intact. Nik Seidenader and Volker Wedershoven remain as directors at the head of the Seidenader companies. All of Seidenader’s 360 or so employees will continue to work at the sites in Germany and the USA. Nik will the production program be affected by the company’s membership of the KÖRBER MEDIPAK Group.

However, there will still be two separate stands at Interpack in Düsseldorf (10 to 18 May): KÖRBER MEDIPAK will be found in Hall 16, Stand A25/B26, with Seidenader not too far away, also in Hall 16 on stand B47. A shared cos-porate image, however, is the first step towards togetherness!
Interpack 2011: Technological highlights for integrated packaging solutions

Once again this year, the KÖRBER MEDIPAK companies are appearing together at Interpack. In Hall 16, Stand A25/B26, Rondo, Dividella and MediSeal will be presenting technological innovations which set the standard for pharmaceutical packaging in terms of efficiency, flexibility and reliability. Seidenader will also be present, in Hall 16 on Stand B47, with its latest inspection and Track&Trace solutions.

Highlight: The “White-Line” concept
Specifically for lot sizes in the 1-2000 blister range, MediSeal, with its innovative White-Line concept, demonstrates an entirely new approach by revolutionizing the supply chain on all levels – in a single step, all individual country variants can be combined into one batch.

Higher plant efficiency and lower production costs
The advantages of White-Line production are impressive. Initial customer experience shows that small lots which previously took 4 days to produce owing to the long changeover times can now be processed in just one day. The concept also allows an extremely fast time-to-market, as production can be started almost immediately after receiving national approval. No lead time for individual films, leaflets and folding boxes is needed, as only an electronic layout is required. This results not only in time savings but also lower storage costs. Also, thanks to demand-based just-in-time production of the lot, the storage and depreciation costs for stored “residual lots” are reduced.

Dividella: NeoTOP 804 TopLoad cartoner with Triple-Mode features high flexibility
The focus this time is on the NeoTOP 804 packaging line. The technical design of the NeoTOP 804 fully meets the requirements of many customers who wish to stack multiple products in the same pack. The concept of the NeoTOP 804 has been extended to include triple-mode configuration for the same economic and flexible packaging of individual products. This unique enhancement enables highly flexible operation, as the NeoTOP 804 can be operated in either Single Mode or Triple Mode. The Dividella NeoTOP 804 on show has a capacity of up to 240 cartons per minute in triple mode and packs pre-filled syringes, vials and a pack insert in a combined pack. The NeoTOP 804 has been specifically designed for applications for which a high degree of flexibility is required and where particularly high output has to be achieved.

MediSeal PUMA300: Combining efficiency and flexibility
With the PUMA300, MediSeal has developed a blister line which combines maximum efficiency, outstanding flexibility and future-proofing: product excellence, upgradeability, modularity and adaptability – these are the key features of the PUMA300. Thanks to the consistent use of servo technology, the number of format parts is reduced to a new industrial reference value, reducing lifecycle costs and production costs. The unique modular concept allows plate-type sealing to complement or replace the standard roller-type sealing, as required. Shortened cleaning time and fast change-over make the PUMA300 extra efficient.

LA600 SP stick pack machine
This high-speed stick pack machine has been specially designed for the pharmaceutical market. The LA600 SP machine featured at Interpack produces more than 600 stick packs per minute on ten tracks and has an extremely small footprint of approximately five square metres.

Also not to be missed at Interpack: the LA160 edge-seal sachet machine – a compact (1 m²) and highly versatile machine. The LA160 is the ideal entry-level model for packaging all pharmaceutical and cosmetic products.

KÖRBER MEDIPAK Group

Register online and secure your admission voucher!
www.koerber-medipak.com/interpack

Körber Medipak
Hall 16, Stand A25/B26

Seidenader
Hall 16, Stand B47

Rondo AG
Hall 7.1., Stand B28

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Packaging from Rondo – for increased security

The Rondo company specialises in packaging development and packaging materials. In addition to its tried-and-tested products, at Interpack Rondo is focussing above all on the theme of packaging security. The new patented Pharma DDS (Discrete Dose Slider) child-resistant pack, which has been jointly developed with Stora Enso, is particularly suitable for packaging for clinical trials. With Rondo’s likewise patented Tamper Evidence® packaging, tamper evidence is integrated into the box.

Seidenader: robot-assisted inspection

Among other things, Seidenader will be launching its new robot-assisted RIM inspection machine at Interpack. The RIM machine has been designed specifically for small batch production, e.g. in the product development environment or in clinical trials, or for products for which automated inspection is preferred because of the nature of the product. Pressure measurement in vials: to protect patients, the FDA demands full integrity of the pharmaceutical container and seal. The Seidenader HSA system measures the pressure in the vial or the oxygen content and can therefore reliably detect leaking containers-in-line, at up to 600 containers/min.

Visit us at Interpack and see for yourself the top quality and outstanding technology of our machines and services.

We look forward to talking with you!
White-Line by MediSeal – Revolutionary supply chain concept for very small lots

The trend towards smaller lot sizes is one which has become apparent in recent years and which will continue to grow. Units of up to 20,000 blisters are as a rule considered to be small lots, where the scale extends down to a lot size of one.

The cause is the increasing competition between pharmaceutical companies in the traditional therapeutic sectors. For this reason, markets which were previously considered too small to be profitable are now being examined more closely. The development of new drugs in new, specific therapeutic areas with a smaller number of potential patients is also becoming an area of growing interest. For the conventional packaging process, however, small lot sizes can mean a massive decline in productivity. Because of the rapidly increasing number of format changes, the efficiency of the packaging lines drops and so the cost per unit of production rises disproportionately. Even though constant improvements are being made in terms of conversion, cleaning and clearing processes, the improvements which are achieved are not sufficient in and of themselves to solve the problem of lots which are getting smaller and smaller.

The LSC®-Late Stage Customization concept – which MediSeal has been offering since 2005 – consists of a variant of partially decoupled processes, so that the blistering, cartoning and printing stages can be carried out independently of each other. This makes it possible to combine small packaging lots on the blister machine and then to customize them in a downstream, decoupled secondary packaging process.

This concept has now been refined and developed consistently. Specially designed for lot sizes in the range from 1 to 2,000 blisters, the White-Line by MediSeal concept constitutes a brand new and innovative approach which revolutionizes the entire supply chain within the company.

All the different country variants are combined into one batch. This enables a change of country variant during a production run within less than fifteen minutes. The production of these “combined batches” takes place within specific, predefined time frames. This eliminates storage, because, depending on the needs of a particular country, the total lot size can be adjusted individually. To achieve these time savings, the production process must naturally apply new procedures. For example, all country-specific elements are “white”, i.e. they are brought onto the line unprinted and then printed inline.

This is what it looks like in detail: Blister printing uses two printers: one device applies a 2D code using UV printing for blister identification, whilst another unit prints the product information in black. To print the leaflet insert, blank paper from the roll is used – one printer respectively prints the front and back. Up to 30 leaflets per minute can be produced. The boxes are usually already printed with the logo and other non-country-specific data. The in-line printing is carried out by four printers in series: one black printer for the front and back, one printer for red, and one printer for application of the Braille text.

By consolidating different country variants, total production time can be reduced by up to a third.
Security through specialised inspection systems

In order to guarantee pharmaceutical safety, multiple inspection systems must be installed on the line to check each blister, each leaflet and each box separately. The three camera systems for the blister printing area verify that each blister is completely filled and inspect the UV code and the black print. Two cameras are used to check the leaflet insert, one for the front and one for the back. The same applies to the box printing: one camera checks the top of the box and another the bottom, and a third checks the Braille text. The biggest challenge is to check the leaflet insert, because this is where the information density is very high. Here a line-scan camera approximately 4,000 pixels wide is used, generating an image with more than 20 megapixels.

All the print data is provided in the form of PDF documents: one document each for the blister, the leaflet and the print on the box. This information is managed in the customer’s ERP system; an LMS (Line Management System) is used as the interface with the printers and inspection systems on the packaging machine. The line itself consists of a CP400 blister machine with an integrated P1600 cartoner, plus an attached weighing system and a table for manual packing. A B1B-ROB module for tidy stacking of the blisters in a hopper can be fitted as an option. Final packaging is not needed for these very small lots. However, the White-Line does not necessarily have to be connected to a blister machine. In the case of a decoupled blister process and packaging process, the blisters have to be provided with blank film and a code system.

“Fundamental optimisation of the supply chain”

The advantages of White-Line production are impressive. Initial customer experience shows that small lots which previously took 4 days to produce owing to the long changeover times can now be processed in just one day. But it is not only line efficiency which can be improved dramatically. The concept also allows for an extremely fast time-to-market, as production can be started almost immediately after receiving national approval. No lead time for individual films, leaflets and folding boxes is needed, as only an electronic layout is required. This results not only in time savings but also lower storage costs. If the layout changes, existing inventory no longer has to be destroyed. Also, thanks to demand-based just-in-time production of the lot, the storage and depreciation costs for stored “residual lots” are reduced.

“With the White-Line we address and solve problems associated with small lots not through machine optimisation, but through further development of the entire production process and, above all, fundamental optimisation of the supply chain”, says Stephan Plewa, CEO of MediSeal GmbH. “In close cooperation with our customers we can achieve benefits which are impossible with traditional packaging lines.”

This year, the White-Line is also the centrepiece of our presence at Interpack! Visit us in Hall 16, Stand A25/B26!

MediSeal
More safety in the box

Occurrences of product tampering with food and beverages, as well as cosmetics and pharmaceutical products, always generate public headlines. They confuse consumers and create a risk for manufacturers and retailers which should not be underestimated. With Rondo Tamper Evidence, Körber Medipak’s Swiss subsidiary company Rondo has developed a folding box with integrated tamper evidence.

“A high degree of effectiveness at low cost

Neither material costs nor investment costs are incurred with Rondo’s patented “folding box with Tamper Evidence”, as it involves neither security labels nor glue. The principle is relatively simple but still offers effective and visible protection. During the sealing process, cut-outs are included in the bottom and top flaps; these clearly and irreversibly indicate the first opening of the box. At first glance, the consumer can see from the break in the perforation whether the packaging is intact or if it has been tampered with. For the product manufacturer, Rondo Tamper Evidence also offers other advantages compared with other methods: Existing cutting tools can be used and slightly modified for the punching process. The blanks can be erected, filled and sealed on existing packaging lines. Nor is the packing rate affected by the Tamper Evident solution. Opening and resealing is just as simple and easy as it is with Rondo’s conventional folding boxes. Even the design of the box benefits from the innovative Tamper Evident solution, as text and logos are not covered by a label.

Applications in various fields

“There is no absolute security against counterfeiting and tampering,” stresses Staub. “Nevertheless, the manufacturer can make a major contribution to improving product safety with our innovative solution and can offer added-value to retailers and consumers”, he notes. Staub sees possible applications for the new folding box with Tamper Evidence in many different areas. There is potential, for example, in the area of OTC products, which are increasingly being sold by drugstores and supermarkets, depending on the respective national legislation. This means that such items are accessible without restrictions to a much wider public, with the resulting greater security risks. But Rondo’s Tamper Evidence will also be of interest in the case of cosmetics and prescription drugs which are at high risk of counterfeiting.
Environmental life cycle assessment

Concepts such as the ecological footprint are doubtless very interesting, but they do not help us to assess the environmental impact which is generated by a single product throughout its life cycle. To do this we must go one step further and apply what is known as the ecological life cycle assessment (LCA) method. LCA is the model for the complex interaction between a particular product and its environment ‘from cradle to grave’.

Step 1 – Inventory (LCI - life cycle inventory): describes the emissions which occur and the raw materials which are used during the life cycle of a product. To make the comparison as objective and scientific as possible, commercially available software was used.1

Step 2 – Assessment: A listing of the impact of these emissions and of the depletion of raw materials.

Using the widely recognised Eco-indicator 99 method2, the damage caused by all the emissions calculated in step 1 to our ecosystems is measured. Finally, individual categories, such as CO2 emissions, can be compared.

Case study – NeoTOP packaging compared to a plastic tray for a six-syringe pack

In this case study we examine the environmental impact caused by two different packs which serve precisely the same purpose in their life cycle – the delivery of six syringes to a hospital. The NeoTOP solution consists of two flat cardboard blanks which are erected automatically by the Dividella packaging machine. The other, more traditional packaging consists of a cardboard box and a plastic tray. The plastic tray is usually deep-drawn on a thermoforming machine and then placed in the cardboard box in the cartoner.

For purposes of illustration, we have looked at plastic trays made from PVC and PP, in order to better clarify the differences between different plastics. In this case, the aluminium tray serves only as a theoretical example, but can easily be applied to tablets, which are packaged in an aluminium blister.

In the scenario, the following aspects were considered:

- Production of raw materials such as PVC, PP, PET and cardboard fibres
- Manufacturing processes such as the production of cardboard and plastic film
- Energy consumption per pack by secondary packaging machines
- Transport of cardboard and plastic over a distance of 100 kilometres to the pharmaceutical plant
- End of life (landfill scenario)

The following aspects were not considered:

- LCA of syringes and patient information, as these are the same for both solutions.
- Transport from the pharmaceutical plant to end users. This subject is covered separately in the section on financial implications.

The life cycles were modeled in the SimaPro software and assessed according to the above-mentioned steps. Figure 1 illustrates the inventory stage and indicates the influence of any form of packaging on different environmental categories, such as “organic emissions” or “climate change”. The latter includes, for example, emissions such as carbon dioxide or methane gas. The results from the database show that the CO2 footprint of the NeoTOP solution over its entire life cycle amounts to about 18 grams of carbon dioxide, whilst the plastic solutions are at about 80 grams and aluminium is at the top of the scale at 155 grams. In short, even if we assume an error bar of 20% in the modelling, the factor for Toploading is 4 to 5 times better with regard to the carbon dioxide environmental indicator.
Financial implications of sustainable solutions

It is not particularly surprising that, as a general rule, more sustainable packaging also saves pharmaceutical companies money. On the one hand there is the cost of the packaging material. The less material used, e.g. an optimised size, the better the solution. Naturally, optimisation of size is not the only parameter in the development of pharmaceutical packaging. For each pack, there can be optimised. Depending on the number of packs produced in a year, these recurring cost savings can be considerable.

However, Dividella has proved on numerous occasions that cost savings of 10 to 40% are possible on packaging materials when switching from combination packs to NeoTOP solutions which consist entirely of cardboard. Savings of 10 to 20% are possible if the size of the two solutions is similar, and 40 to 50% if the size can be optimised. Depending on the number of packs produced in a year, these recurring cost savings can be considerable.

Of course, the smaller size of the densely packed NeoTOP solution (thanks to the cardboard flutes preventing contact between the glass components) has a major effect on the transport costs of refrigerated goods. As an example, we have calculated the annual savings for a four-syringe pack (NeoTOP compared to a plastic tray in a side-loading box) which is currently on the market. If one assumes a volume of 2.5 million packs per year and an average shipment distance of approximately 2,600 km per vessel, the savings amount to about one million US dollars a year. For air transport of the same volume, these savings amount to about 10 million US dollars.

It goes without saying that the precise savings depend on the logistics, such as the type of transportation, distribution channel and network, and the number of packs. The above examples clearly show that material and transportation costs for solutions which are also environmentally sustainable can be considerably lower. For secondary packaging of pharmaceutical products, there has not so far been a single case in which the ecological and economic aspects contradict each other.

This article presents a method for analytical measurement the impact of different products and services on the environment. The LCA method allows customers to evaluate packaging solutions and to select those which reduce their own ecological footprint. In general, this environmental ranking goes hand in hand with the economic ranking. In other words: sustainable packaging solutions also bring significant cost savings.

1 SimaPro by PréConSultants (www.pre.nl)
2 Eco-indicator 99 impact assessment method – report available at www.pre.nl