



KÖRBER MEDIPAK
pharma packaging systems



2|2011

**Identification and
traceability –
a global requirement**

facts

KÖRBER MEDIPAK - Customer Magazine

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Dear Customers,



The World Health Organisation (WHO) estimates that up to 15% of the pharmaceutical products sold worldwide are counterfeit. This corresponds to a value of \$US 75 billion. This problem crossed the frontiers of the developing countries some time ago: globalisation and the trend towards liberalisation of markets for pharmaceuticals are making counterfeiting a growing problem in the industrialised countries too. More and more countries are drafting standards which ensure full traceability, to prevent counterfeiting of drugs and to improve patient safety. This, in conjunction with the financial costs associated with counterfeiting, is prompting many pharmaceutical companies to introduce serial numbering of their products.

As pioneers in Track&Trace systems, Seidenader provide solutions for all stages of packaging. Depending on customer needs and country-specific requirements, variable labelling and identification systems can be incorporated; for the smallest sales unit, for aggregation on the next packaging unit up or as a data management system for complete packaging lines. The focus is on the customer's existing equipment and the goal is to establish flexible, upgradeable systems which maintain the efficiency and profitability of the plant.

The Borisov pharmaceutical manufacturer in Belarus has deliberately opted for the Dividella TopLoading concept. One key factor in the purchase of the NeoTOP904 was the monomaterial packaging, made from cardboard, which can be produced economically in Belarus and which also meets the requirement for sustainability.

Rondo AG has also invested in security in the packaging of pharmaceutical products. The unique Speedmaster XL offset press from the German manufacturer Heidelberger Druckmaschinen sets the standard for quality and safety in packaging printing. This unit has been in operation at the Allschwil site in Switzerland since September 2011.

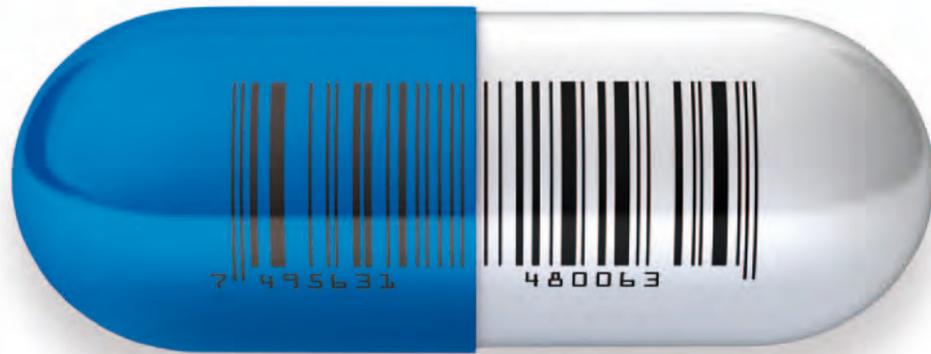
Sustainable concepts for small lot sizes begin at the design stage. Even MediSeal's standard blister machines therefore provide the technical basis which may be needed later on for packaging the smallest lot sizes at line level. Both the White-Line logistics concept and the LSC® Center and BIB-BOB concept are based on the same basic models of the MediSeal CP200, CP400 and CP600 blister machines. This genuine modularity allows customers to adapt the use of a packaging line throughout its life cycle.

I hope you enjoy reading this issue and look forward to your feedback!

My very best wishes,

Gerhard Breu

Identification and traceability of pharmaceutical products – a global requirement



Counterfeit drugs are now a global problem. For example, fakes account for about half of all internet orders. According to estimates by the WHO (World Health Organisation), up to 15% of all medical products worldwide are counterfeit. In 2010, these were worth \$US 75 billion and the figure is growing. This not only leads to significant losses for the pharmaceutical industry but above all puts the health of patients at risk and undermines their trust in medicines.

Security and flexibility

To ensure patient safety, therefore, clear traceability is required throughout all stages of the packaging process. Already enshrined in national law in some cases, Track&Trace solutions will be essential in the future for all pharmaceutical manufacturers. However, the industry's requirements of such systems go far beyond the traditional batch traceability. Flexibility in identification and verification, integration into existing systems, and quick format changes, without compromising plant efficiency: these are the challenges for Track&Trace solutions.

Seidenader is one of the pioneers in the development of system solutions for Track&Trace applications. A combination of engineering knowledge, experience of industrial image processing and know-how of programming appropriate software enables Seidenader to develop flexible Track&Trace systems. Tailor-made solutions are designed, depending on customers' requirements and taking existing systems into account: from serialization of the smallest packaging unit to complete line management systems.

Technical implementation

Within the packaging process, integrated coding stations, code readers and image processing systems provide the necessary data for the product code which makes full traceability of pharmaceutical products possible. Seidenader applications can be integrated into existing packaging machines but can also be used as a stand-alone solution. It is possible to tie the system into an existing IT environment inline or offline or to link it as an isolated application via an interface to possible external databases and/or MAS and ERP systems.

Depending on the specific structure (set-up), serial numbers are imported into the Seidenader system or created directly within the system. The printed data is checked by image processing systems, barcode readers or RFID readers. The database generates comprehensive evidence along the supply chain – including records of product losses, units damaged and replaced during the packaging process and samples taken.

Seidenader is a long-standing partner of pharmaceutical manufacturers and all its T&TSolutions meet the stringent standards of the industry, as well as the requirements of 21CFR Part 11, cGMP and GAMP.

Expandable Track&Trace systems

In order to provide sustainable, future-proof solutions, Seidenader develops expandable Track&Trace concepts. Once installed, components can be expanded as needed (fig. 1).

Phase 1 – Application and verification of the serialized code and readable text on the smallest retail unit.

Typically the **Seidenader T&T SingleUnit** consists of a conveyor with a coding station and a code reader, plus an ejector unit and a line controller (a PC with a data management system). A T&T SingleUnit is positioned inline after a cartoner or a weighing unit. In the offline version, the products are fed manually. Alternatively, the printer, reader and reject unit can be integrated into existing packaging machines.

Phase 2 – Aggregation

Identification and recording of data on products which are assembled into the next larger packaging unit (bundle, case, pallet), plus application and verification of the serialized information relating to the parent packaging unit (fig. 2).

Depending on the legal requirements of individual countries, the degree of automation and the specific processes of each packaging line, Seidenader T&TSolutions can be extended to the packaging stages for bundles, cases or pallets. The data collected in all stages of packaging for a product are associated in the T&T LineController with the data of each generated code. Ejected packaging is removed and can be processed using the handheld scanner. In collaboration with the customer, Seidenader produces tailored designs: for manual or automated processes, based on scanners or image processing systems, integrated or stand-alone. Since Seidenader T&TSolutions are modular, standard components can be used to configure customer-specific applications.

Seidenader T&TSolutions also allow the integration of warehousing. T&T Warehouse comprises a terminal with a Track&Trace software package, plus handheld scanners and label printers for order picking.



Seidenader

Phase 3 – Data management systems for multiple production lines

The data management system Seidenader „Multi Line Server“ (MLS) is a hub (interface), which can be linked both to upstream systems (e.g. ERP/MES/EPICS) and to multiple downstream line control systems. At the end of the production, the individual line controller transmits data on lot sizes, quantities, and serial numbers relevant to the supply chain to the MLS.

If required, all the components of a production line or the entire production of a plant can be controlled using Seidenader line management system: SCADA, alarm circuit, access management, compliance with 21 CFR part 11, recipe control.

Summary

The design and integration of complex Track&Trace solutions into existing processes is a challenge which can best be met by a systems provider. The decisive factor is the understanding of the packaging process as a whole, in order to be able to offer realistic solutions at all levels.

Figure 1: T&TSolutions are divided into three phases

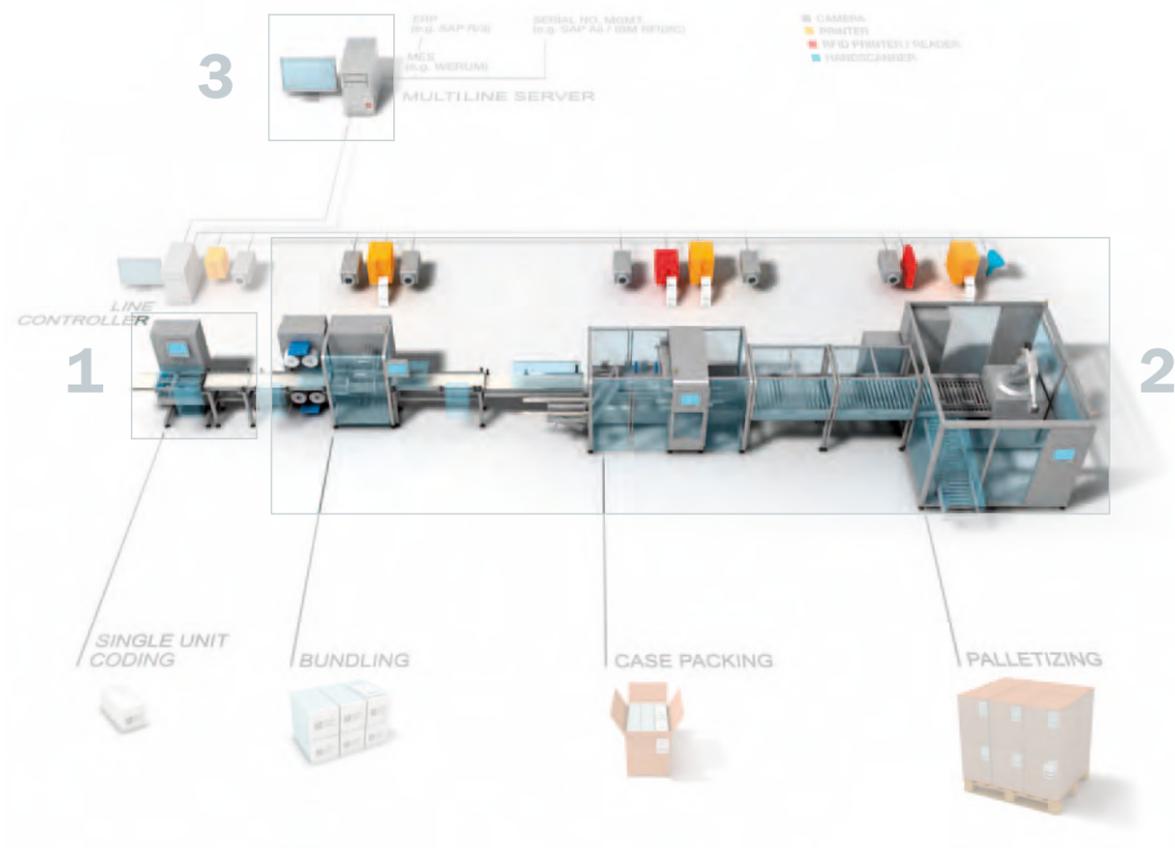


Figure 2: Manual aggregation line



E-pedigree and serialization

An e-pedigree is an electronic record of the entire product cycle. It contains accurate and complete information about each transaction within the extensive supply chain.

Serialization is the process by which every sales pack, bundle, case and whole pallet receives a unique and above all traceable serial number. For product information exchange, 2D-matrix, barcode and RFID technologies can be being used. For worldwide exchange, the international standards (e.g. GS 1 standards) must also be met.

State guidelines for the identification of medicines

| | |
|---------------|--|
| USA | 2015 expected for every drug |
| Turkey | Phase 2 will start in 2012 |
| Europe | EU directive on implementation in national law by 2013 |
| Brazil | in progress |
| China | in progress |

The introduction of serialization may be seen as a costly commitment but also offers the pharmaceutical industry a range of benefits:

- Improved patient safety creates confidence
- Forgeries are detected faster and therefore eliminated faster
- Transparency in the production process enables cost-optimized storage
- High-quality medicines are better protected
- Identification and reduction of grey-market and parallel products
- Recalls are simplified

Serialization and an e-pedigree allow full traceability of the product from the retailer back to the manufacturer and therefore create a better situation for all those involved. They promote the reduction of counterfeit products and the greatest possible patient safety.

Dividella successful with NeoTOP904 at Borisov in Belarus

More than 200 products in eleven pharmaceutical groups, 300 in-house technological developments and 45 years of company tradition: Borisovskiy Zavod Medicinskih Preparatov is the most important and largest pharmaceutical manufacturers in Belarus. Last year alone, nine pharmaceuticals were developed which can replace previously imported products. Borisov is on the road to success: in 2013 another US\$ 53 million plant currently under construction will open, operating according to GMP guidelines. Even though about 60% of sales are generated by exports, Belarus remains one of the most important markets.



The pharmaceutical company from Borisov in the catchment area of the capital Minsk is not resting on its laurels. Hi-tech will ensure the continued expansion of success in the market.

For example, in late summer last year a NeoTOP904 from Dividella AG of the Körber Medipak Group was brought into operation. By October 1st of last year, just under 500,000 packs for ampoules and about 3,500 packs for vials had been produced.

Bringing the high-performance system from the NeoTOP family online has saved significantly on costs, as the vials were previously packed by hand. At the same time production volumes have increased considerably – with significantly less manpower. Freed-up personnel can be redeployed within the factory. Today, only two workers are needed to operate the NeoTOP904.

The packaging lines in the NeoTOP series of machines erect and glue folding boxes from bought-in flat cardboard blanks. The dividers needed for product protection are, like the boxes themselves, formed from a flat blank. A key feature: this is mono-material packaging based on cardboard.

The NeoTOP series of machines consists of four semi-automated and fully automated versions. Borisov chose the top-of-the-line model, the NeoTOP904. The individual versions of the machine type can be configured in the Dividella factory to suit customers' specific needs. They cover all performance categories for packaging different lot sizes in the pharmaceutical industry.

The sale to Belarus was handled from Switzerland in collaboration with the Moscow agency. This agency is responsible for the introduction of Dividella and Körber Medipak products in Russia and the CIS.

Vitaliy Deresh is the company's CTO (Chief Technical Officer). In an interview with Körber Medipak facts, he comments on the background, achievements and prospects of cooperation with Dividella.



Vitaliy Deresh
CTO (Chief Technical Officer)
Borisov

facts: Vitaliy Vassilevich Deresh, what characteristics of Dividella and NeoTOP as a packaging machine were of interest to Borisov?

Deresh: *The purchase was based on a painstaking decision-making process. For example, we identified the number of packaging lines necessary for a possible medium-term sales increase.*

At the same time, offers from a range of vendors and different machine variants were examined. However, what appeared to be particularly attractive to us was the fact with the NeoTOP solution cardboard alone is used for the packaging. This is a key aspect. Cardboard is also produced in Belarus. All the competing products use PVC, aluminium or other materials in addition to a folding box.

Another reason lies in the manufacturer itself. Dividella is part of the Körber Medipak Group, one of the market leaders in the challenging pharmaceutical packaging solutions sector. This augurs well for reliability in the operation of the machine.

How quickly did you decide on the NeoTOP904 – and what competition was this machine up against?

Deresh: *The legislation of the Republic of Belarus generally stipulates an open tendering procedure for such investments. Apart from Dividella, a number of well-known companies from Germany, Italy and Switzerland were involved.*

Mr. Deresh, how do you assess the cooperation between Borisov and Dividella during the project phase?

Deresh: *The level of organization at Dividella is remarkably efficient. Problems and questions which arose during the project were in many cases answered and resolved within a few hours. Even in contentious cases, we were able to quickly arrive at a satisfactory arrangement.*

How has production changed, now that Borisov has brought the NeoTOP904 into operation?

Deresh: *The most obvious change concerned the packaging of vials with powder for injection. The packs used to be inserted into the secondary packaging by hand; this is now automated. After installing the NeoTOP904, we were therefore able to redeploy a number of employees elsewhere in the company, as just two people are needed to operate the machine.*

Another benefit was the reduction in the load on the packaging lines previously used, which beforehand we had to utilize to their capacity limit.

To what extent are you currently using the NeoTOP904?

Deresh: *The line is working for us in three shifts, seven days a week.*

How satisfied are you with the performance of the system? Are there any anomalies or susceptibilities to malfunction?

Deresh: *Not that I can determine, with regard to the technology. All the components used were from leading European manufacturers. And in the event of downtime, the modem link with the service centre in Switzerland provides valuable assistance. This networking permits rapid fault diagnosis, and downtime can be minimized.*

Does this mean that you will consider Dividella equipment for your future plans?

Deresh: *The development and investment plan for Borisov envisages for four additional ampoule filling lines for 2013 to 2015. When calculating the required additional packaging systems, the data relating to the NeoTOP904 was naturally incorporated.*

Vitaliy Vassilevich Deresh, thank you very much for this interview.

fig. above: Dividella's NeoTOP904 operates in 3-shift production.

fig. alow: The reclosable TopLoading packaging made of carton



TopLoading by Dividella

The NeoTOP family, in different performance classes ranging from semi-automated to fully automated, is superbly suited to the growing diversity of secondary packaging in the pharmaceutical industry. It is suitable for packaging in resealable TopLoading boxes with built-in dividers. After the pack is erected from the supplied flat cardboard blanks, dividers are formed from a second flat blank and glued into the erected box. Parenteral products such as ampoules, vials, syringes, pens, lancets, needles, instructions, etc. are then inserted on the line. Depending on the model, filling takes place by hand or using the fully automated equipment. The modular packaging machines can handle from ten to 240 packages per minute and are configurable to customers' specific requirements.

More information:
www.dividella.ch/en/solutions/toploading

We'd like you to meet ...



Yuliya Sayenko
 Product Manager
 Dividella AG

In May 2011 Yuliya Sayenko joined Dividella AG as Product Manager. She is a graduated mechanical engineer and has 15 years of professional experience. After receiving her Master in environmental management at the University of Basel Yuliya Sayenko worked for Siemens Energy Division with main responsibility for strategy and business development.



Virginia Tyson
 Customer Service
 Representative, Rondo-Pak

Virginia Tyson, age 44 joined Customer Service at Rondo-Pak Norristown, PA in August 2011. Prior to that, Virginia worked for 3C Packaging's Northeast Division as Customer Service Manager and Dee Paper Company in Chester PA working her way from Order Entry up to a position on the Senior Management team. Virginia went to DCCC and Neumann University studying Business Management.



Speedmaster XL 105-10-P+LX3,
sheetfed offset machine

A new benchmark for quality in packaging printing

Rondo AG has made an investment in safety. Since July 2011, one of the very latest sheet-fed offset printing presses has been in use for packaging printing. The printing system sets new quality standards in the production of pharmaceutical packaging.

All those who entrust their production to Rondo AG rely on high product safety. The company is meeting this challenge with its ongoing investment in the latest production technology and process engineering. In the folding-box cutting and gluing section at the Allschwil site no machine is more than three years old, says Alfred Kälin, Head of Innovation & Services.

In the upstream packaging printing section, Rondo AG also has modern machinery. The average age has just come down significantly with the commissioning of a brand new offset printing press from the German manufacturer Heidelberg Druckmaschinen AG. The purchase of the new machine is part of the ongoing project of investment in buildings and production technology at its sites in Allschwil, Switzerland and Ejpvovice near Pilsen in the Czech Republic.

Unique in the world

For one and a half years, alternatives were meticulously evaluated on the basis of a 46-point rating matrix. After numerous discussions and visits to packaging printers in Switzerland and Germany, the decision was taken to opt for a solution which is unparalleled to this day. As Alfred Kälin puts it: *"This high-performance printing system is equipped with innovative features which are not in use on any other packaging printing press in the world. With regard to the stringent security requirements of the pharmaceutical industry, the machine brings a whole new level to quality printing on packaging."*

With a sophisticated monitoring system each individual blank is accurately recorded, at speeds of up to 15 000 sheets per hour.

The high-precision system detects even the smallest irregularities in the printed image and ensures that faulty boxes are automati-

cally diverted from subsequent processing. The fact that the switch is no longer used for the whole sheet, but only for each defective blank means that the new quality assurance approach also has a significant impact in terms of cost savings and lower paper consumption.

New solutions for new needs

The Speedmaster XL 105-10-P+LX3 offset printing press features a ten-colour configuration with a downstream coating station and modular driers. A device between the second and third printing unit enables the sheet to be turned automatically during the printing process. In addition to the continuous ten-colour printing with coating, the 2/8 variant is also possible, with two-colour printing on the inside of the pack and eight colours on the outside. Alfred Kälin explains: *"At present, instructions for the end user are still printed in monochrome black text on the inside of folding boxes."* →

Rondo

Since July 2011 in production: the worldwide unique high-performance printing system.



Today's machines are also equipped as well with a turn between the first and second printing unit. We are working on the assumption, however, that there will be an increasing demand for two-colour print on the inside of packaging. In certain markets, pictograms are required instead of text. In view of this development, the new press means we are very well prepared for highly efficient, cost-effective production."

An important part of the sheet reversal process is a system for applying UV-curing printing inks. A so-called intermediate drier ensures complete curing of the inks applied on the inside, just before the sheet is transferred to the next printing unit. Impeccable quality is therefore guaranteed throughout the printing process.

The dimensions of the new offset press are also impressive. The colossus weighs 92.9 tons and is 27.9 metres long overall. The operation and control of the highly automated system, as well as the monitoring of the production and maintenance processes, is carried out at the central console with its integrated large screen. The waste heat from the system with all its peripherals is incorporated into existing energy recovery system.

After completion of the qualification and commissioning work, the system went into production at full output in September.

MediSeal

Sustainable "Small Lot Solutions" start at the design stage

As a result of growing competition and increasing regulatory requirements, conditions in the pharmaceutical market are becoming increasingly complex. The demand for improved patient safety and increased protection from counterfeiting on the one hand and decreasing lot sizes and reductions in health care costs on the other mean that the efficiency and flexibility of the packaging process are becoming a key element in the value chain within pharmaceutical companies.

The trend towards ever smaller lot sizes, engendered by a more comprehensive product portfolio, the shortest possible time-to-market and lead times and more expensive packaging, is causing more downtime and therefore lower plant efficiency. The actual packaging process is interrupted more and more for cleaning and change-overs.

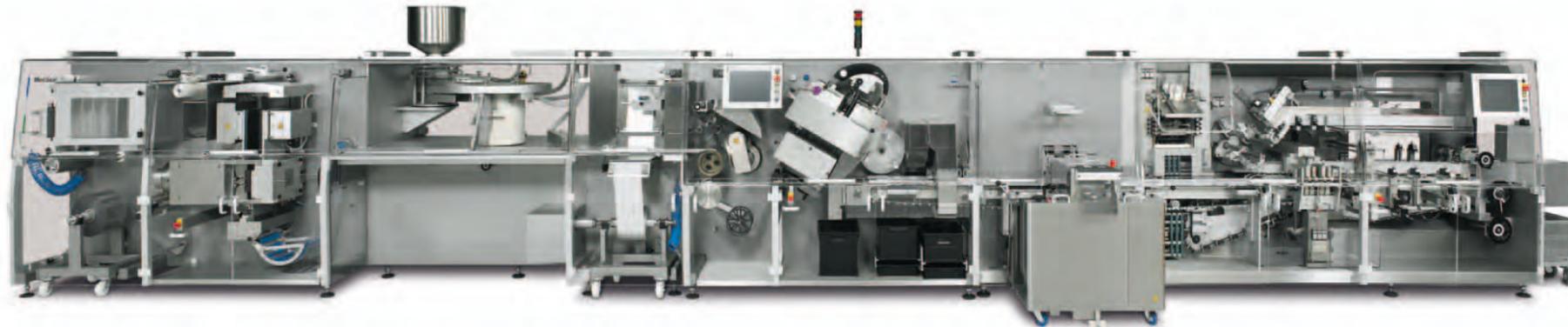
This is where the MediSeal product portfolio offers various levels of the basic concept of the „Small Lot Solution“, depending on customer requirements. The high-end corporate-level solution is undoubtedly the unique White-Line concept by MediSeal (see facts 1|2011).

Flexibility and site efficiency thanks to genuine modularity

All Small Lot Solutions from MediSeal are based on the same concept of standard machines. The technical basis for solutions with high efficiency is built in as early as the design stage. This means that both the White-Line →



MediSeal



Production of unfinished blisters with MediSeal BIB-BOB modules

Fig. 1: LCS® – Late stage customization



- Bulk magazine for:
- storage
 - manual cartoning
 - transport to other sites

LSC® Center with DoD print and cartoning: Ensures flexibility while your conventional lines package large lots

concept and the LSC® Center and the BIB-BOB concept are based on the same modular machines in our CP200, CP400 and CP600 blister machine family.

Their unique modular and flexible design provides the foundation for packaging of small lot sizes at line level. The basis is laid for high line availability and fast change-over processes; this can then be expanded to create customized, integrated logistics concepts.

Even the standard machines are set up for automatic emptying of the line at the end of a batch. User-friendly push-button film insertion makes film changes significantly easier. Excellent accessibility and special cleaning channels ensure simple and efficient cleaning of the machines. Fast access to the machine supports fast, tool-free changing of format parts. On MediSeal machines in general the number of format parts is kept to a minimum at the design stage.

MediSeal's blister machines assure a fault-tolerant and reliable packaging process with outstanding MTBF* times – which means we can guarantee verified rated outputs per format part on our machines.

This genuinely modular design makes it easy to add additional functionality even during the later stages of the life cycle of a machine and thereby adapt to future requirements.



(* MTBF mean time between failures)

We'd like you to meet ...



Dr. Rüdiger Freier
CEO Rondo

As of 1 July 2011 Dr. Rüdiger Freier has taken charge of Rondo AG and its subsidiaries Rondo obaly and Rondo-Pak as CEO. Dr. Freier studied chemistry at the University of Saarland and received a PhD in chemistry. He has long-standing management experience in the pharmaceutical industry, latterly as Managing Director of Swiss Caps AG. Prior to this he held positions in the fields of business development, product development as well as production and quality management. The 53 aged Rüdiger Freier is married and has 2 children.



Mirko Grabow
Key Account Manager
Rondo AG

Since October 2011 Mirko Grabow (36) has been employed as Key Account Manager at Rondo AG, Allschwil. He brings 10 years of sales experience in Europe. For the last 7 years he has worked in sales for a leading supplier of fine chemicals to the chemical/pharmaceutical industry. He was responsible for market development in several European countries. Grabow achieved a degree in economics/international economics at the University of Hamburg and the Université de Nantes.

MediSeal

Another advantage is the possibility of cross-portfolio, module-specific training. Operators who are trained on a CP400 can also operate a CP600.

Optimized design for high plant efficiency: a solid foundation for fast format changes and an essential basis for plant efficiency with small lots processed on basic machines at line level (fig. 1).

Combining lot sizes economically

Even better than short change-over processes: minimizing non-productive time during production. This is where the LSC® Center and the BIB-BOB system demonstrate their strengths: on one site, multiple small production batches are economically combined and packaging production can be set up at virtually the "last minute". Here too, the modular structure of MediSeal blister machines demonstrates its advantages: the sub-processes of blister packaging, printing and cartoning can be linked together based on requirements. Using a mobile logistics module – the BIB-BOB module – you gain flexibility and increase the efficiency of your system. The core of this concept is to take blisters from a MediSeal thermoforming machine and buffer them in a bulk magazine (BIB mode) or to take blisters from this bulk magazine (BOB mode) and feed them on to a cartoner. Depending on requirements, the specific features of the packaging, i.e. printing with specific information, can be applied both inline on the blister machine and at a later time when the blisters are returned to the cartoning machine.

With these comprehensive Small Lot Solutions from MediSeal, efficiency gains of up to 30% can be achieved depending on the individual production matrix.

At a glance

- MediSeal lines are configured according to individual requirements and based on proven modular elements
- Future expansions are taken into account as early as the design stage
- Special modules can be developed and added at any time
- The intended use of a MediSeal packaging line can be adapted in the course of its life cycle
- Modules can be individually developed. A special application therefore bases on tested and proven individual functionalities

Show Previews 2011_12

Pharmtech

November 22 – 25, 2011 | Moscow (Russia)

P-MEC India

November 30 – December 02, 2011 |
Mumbai (India)

Pharmapack

February 15 – 16, 2012 | Paris (France)

Easy Fairs Verpackungen

April 24 – 25, 2012 | Hamburg (Germany)

Interphex

May 01 – 03, 2012 | New York (USA)

FCE Pharma

May 29 – 31, 2012 | São Paulo (Brazil)

ACHEMA

June 18 – 22, 2012 | Frankfurt Main (Germany)



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