

Safe and reliable packaging: KOCH medplus



KOCH expertise
in packaging
applications for the
medical industry



Meet exacting needs with one hundred percent reliability – with modular machine technology **medplus**

Validation-compliant packaging of the most sensitive products

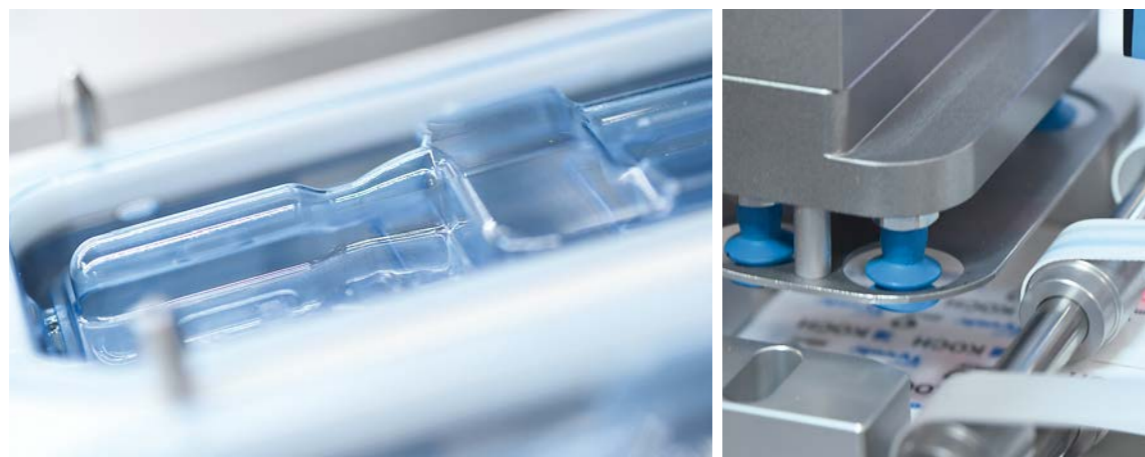
Innovative technology, combined with broad experience, is the basis upon which we develop and implement customized machine solutions for the packaging of sensitive medical devices and pharmaceutical products in transparent, rigid blister packs. Packaging solutions that comply with current directives – EU, FDA, DIN, ISO – and guarantee a cost-efficient and reliable packaging process: whether the semi-automated sealing of preformed blisters, a fully automated forming, filling and sealing process, or the integrated processing of a product, from feeding to end-of-line packaging.

Flexibility as foremost principle

Whether small, medium or large batches, single products or sets, the finest dental drill or voluminous inhalers: KOCH packaging technology medplus is as individual as your products and specifications. The key criterion for all KOCH blister machines is flexibility, achieved on the basis of a modular design concept. Every machine comprises a basic module as well as additional components. These include film and card feeders, robot handling systems, as well as inspection and marking systems for traceability in compliance with UDI (Unique Device Identification) or tracking and tracing requirements. We integrate the elements needed to provide you with a highly efficient packaging process.

Safety and quality redefined: KOCH medplus

We meet the more stringent demands posed by the medical industry on your packaging process with the equally exacting brand KOCH medplus. The name stands for our expertise and experience in this sector. It is a quality mark denoting added reliability, added technology, added attributes, and added support.



- **Medical devices and pharmaceutical products safely packaged**
- **Sterile medical devices:** filters, catheters, needles, intravenous drips, multipart infusion sets, inhalers, surgical instruments, suture material
- **Liquids:** syringes, ampoules, vials, bottles, and pen injectors, single or in sets, sprays, paste-like products
- **Solids:** tablets in wallets or individual weekly blister packs
- **Implants:** artificial joints, stents
- **Dental products:** single or multipart dental instruments, dental drills, dental implants
- **Diagnostic devices:** dosimeters, matching and calibrating material, reagent test strips, quick tests, diagnosis sets

medplus

■ Added value of the brand medplus

- Individual project management by a team of multi-disciplinary specialists
- GMP machine design, machine construction according to GEP standards: no hollow areas, closed cable ducts, special lubricants, superior surface quality
- Hygienic design: easy cleaning, use of medically appropriate materials
- Cleanroom compatibility
- Calibration of relevant process parameters for reproducible packaging quality
- Qualification and validation documentation in accordance with GMP, GAMP5, ISO, and FDA
- UDI-compliant marking and inspection, data acquisition and management

The brand for the optimized packaging of medical devices: KOCH medplus

Special skills in machine construction and consultation

Safety, flexibility, and traceability: these are the three key factors when it comes to the planning of a blister machine or line for the packaging of devices for the medical industry. Full insight is needed: into the susceptible products, the exacting marketplace, and the particular specifications governing both packaging and the packaging process.

In our business unit serving the medical industry, a team of development, design, production, sales, programming, final assembly, and machine qualification specialists focuses solely on transforming your needs into the best respective packaging process. We offer our expertise from the outset, provide advice at all stages, take over full implementation, and manage the project from start to finish.

Packaging technology with added value

In the same way that we offer added advice and support, the brand name KOCH medplus stands for a wide range of features and associated services. Whether a standard machine, a special complex machine, or a highly flexible KOCH packagingLine: GMP-compliant design and construction according to GMP standards are as equally as important as cleanroom compatibility. Detailed documentation confirms the implementation of all defined specifications, thus verifying full functionality.

Medical measuring device in a blister with lid material from the roll



Multipart sterile filter housing with tube and cable set



Blister pack containing syringes

Each complements the other: product, blister type, and packaging solution **medplus**

Straightforward to complex blister packaging

Whether medical devices or pharmaceutical products: the blister pack should be easy to handle, the product protected against external influences, and – particularly important in the case of sterile goods – completely tight to maintain a hygienic environment until the pack is opened. Furthermore, the packaging process should be reliable and cost-effective.

We combine these requisites, and provide the right type of blister and customized packaging technology from a single source. In cooperation with you, we attune the blister design to your requirements and the technical capabilities of your new machine, thus ensuring a smooth packaging process from the start. Every medplus solution strictly adheres to the specifications governing primary

and secondary packaging, and takes appropriate account of the production form and costs: simple and low-priced for inexpensive goods in large quantities, and more sophisticated types of packaging and machine technology for products of higher value.

Central element is an individually configured KOCH blister machine. This comprises a basic module for forming, filling and sealing (FFS), or just for sealing (S), plus the respectively required additional components. Also part of the ideal packaging solution is the selection of suitable materials: APET, PETG, or PLA as blister forming material; paper, card, Tyvek®, or foil as lid material. We also guarantee the economical use of materials. If required, the separate recycling of the packaging materials can also be taken into account.

Face seal blister

Reasonably priced production form, e.g., for low-priced mass products



- | | |
|-------------|-----------------------------------|
| ■ S sealing | ■ FFS forming/
filling/sealing |
| ■ KDT | ■ KBS-PO |
| ■ KS-PO | ■ KBS-PL |
| ■ KS-PL | ■ KBS-KF |

Packaging process:

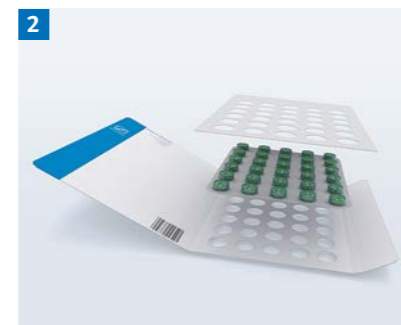
- Rectangular blister smaller than the backing card
- Sealing of the blister to the ready-made card

Optional:

- Semi-automated, just with sealing of the preformed blister

Trapped blister/wallet

Optically superior pack, e.g., for tablets



- | | |
|-------------|-----------------------------------|
| ■ S sealing | ■ FFS forming/
filling/sealing |
| ■ KDT | ■ KBS-PO |
| ■ KS-PO | ■ KBS-PL |
| ■ KS-PL | |

Packaging process:

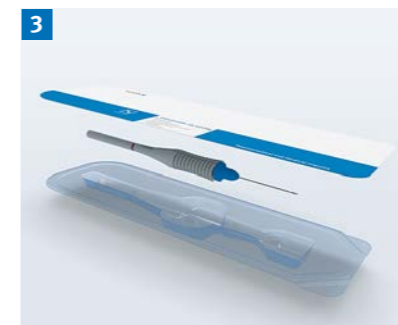
- Forming, filling, and sealing of the blister
- Placing of backing card, blister, and front card
- Sealing of front and back card with blister
- Folding to required wallet version

Optional:

- Semi-automated, just with sealing of the front and back cards
- As reclosable wallet

Blister with lid material from roll

Tight pack, e.g., for sterile products



- | | |
|-------------|-----------------------------------|
| ■ S sealing | ■ FFS forming/
filling/sealing |
| ■ KDT | ■ KBS-PO |
| ■ KS-PO | ■ KBS-KF |
| ■ KS-PL | |

Packaging process:

- Forming, filling, and sealing of the blister
- Cutting or punching of the blister

Optional:

- As reclosable wallet

Blister to blister (double blister)

Transparent pack, e.g., for immediate recognition of product variations



- | | |
|-------------|-----------------------------------|
| ■ S sealing | ■ FFS forming/
filling/sealing |
| ■ KDT | ■ KBS-KF |

Packaging process:

- Forming of two identical or differing blister halves for the front and back
- Filling of one blister half
- Sealing of the two halves
- Cutting and/or punching of the blister – only possible with KBS-KF

Clamshell

Versatile pack, e.g. containing more than one of the same product



- | |
|-----------------------------------|
| ■ FFS forming/
filling/sealing |
| ■ KB-KF plus KS-PL in line |

Packaging process:

- Forming and cutting/punching of the open halves
- Filling of the preformed halves
- Closing of the clamshell

Optional:

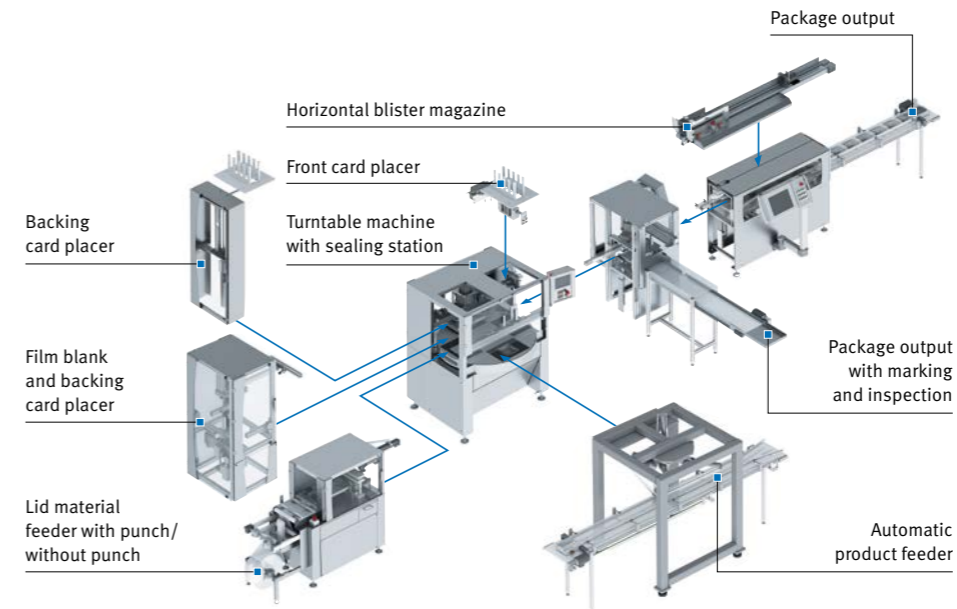
- As reclosable wallet

Variable, compact form: fast, straightforward, cost-effective sealing

Turntable Machine KDT medplus



Turntable Machine KDT, here the basic version, in GMP-compliant medplus design



Modular configuration of the Turntable Machine KDT medplus

The Turntable Machine KDT medplus has all the attributes needed for the cost-effective packaging of small to medium batches: low initial outlay, reasonably priced format parts, economical energy consumption, and a well-devised machine concept with state-of-the-art technology. The basic machine version incorporates a turntable with four sealing tools and a sealing unit for thermal sealing.

Extension options

An additional card placer system allows the automated feeding of different pack parts such as blisters, lid material from the roll, or as blanks or front cards for trapped blisters. A product feeder and other components are available for an automated solution.

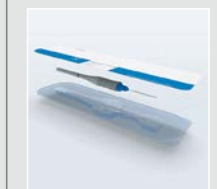
Blister types



Face seal blister



Trapped blister/wallet



Blister with lid material from roll



Blister to blister

Technical data

- **Blister depth:** up to 70 mm
- **Sealing format:** 250 x 360 mm
- **Sealing force:** 30 kN
- **Output:** 12 cycles/min., depending on forming material, blister shape/size, and sealing duration

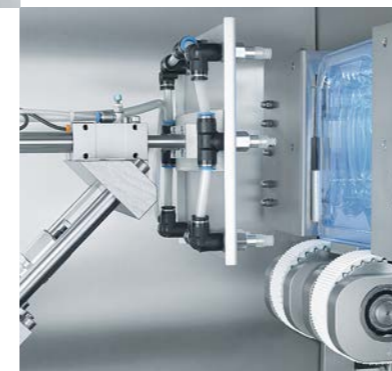
Benefits

- Low capital costs
- Reasonably priced format parts and fast format changeovers
- Small footprint and low energy consumption
- IPC control system with touchscreen, optionally with modem connection for remote diagnosis
- Mobile as fitted with lockable casters



Above: Turntable with 90° cycle

Right: Automatic placing of blisters taken from the magazine



Throat lozenges in a blister wallet

Format and product diversity: hygienically packaged on a small footprint

Sealing Machine KS-PO medplus and Blister Machine KBS-PO medplus with oval pallet transport



The compact Sealing Machine KBS-PO medplus: easily accessible from all sides

The Blister Machine KBS-PO medplus is based on a systematic, detailed concept for the reliable, productive, and cost-optimized packaging of small to medium batches. It forms and seals blisters in a fully automated, end-to-end process. The machine operates with utmost precision at a speed of up to 14 cycles per minute. The large format area and the generous forming depth permit the packaging of bulkier products. Should the handling of preformed blisters be required, configuration with the Sealing Machine KS-PO medplus is recommended.

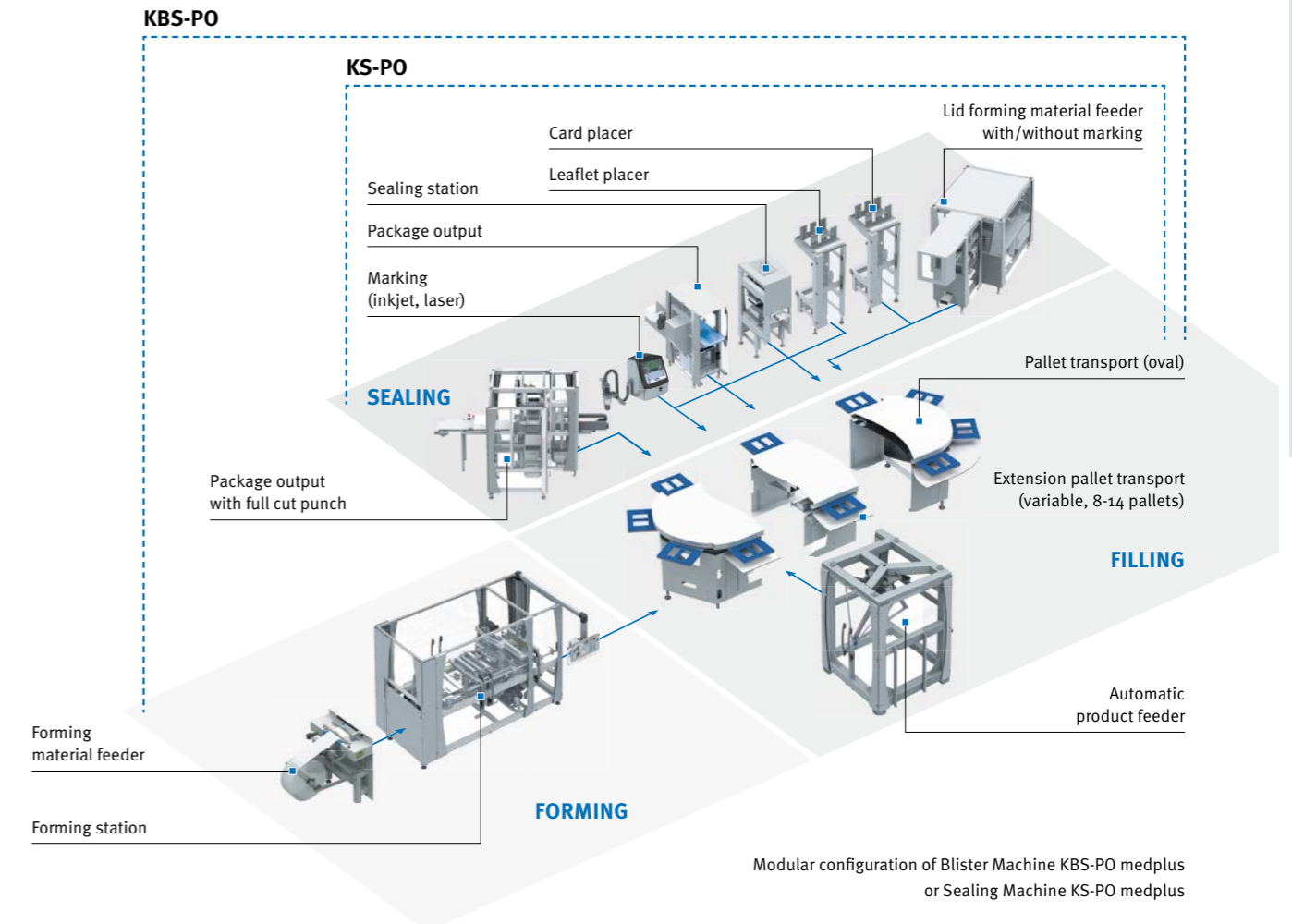
Special feature of both machines is the oval pallet transport. The integrated, space-saving pallet section is easily accessible and can be conveniently loaded by several persons. The tool-free exchange of the sealing tools and fast, straightforward format changeovers guarantee maximum flexibility and productive packaging, also when handling small batches.

Above: Plaster box in blister sealed with Tyvek®

Below: Pallet transport system at ergonomic height for blister loading



- **Technical data**
- **Blister depth:** max. 100 mm
- **Forming area:** 250 x 350 mm
- **Sealing format:** 250 x 342 mm
- **Output:** 14 cycles/min., depending on forming material, blister shape/size, and sealing duration
- **Benefits**
- Flexible machine concept for the efficient packaging of different formats
- Low capital costs
- Tool-free retooling and quick format changeovers
- Compact machine design with small footprint



Modular configuration of Blister Machine KBS-PO medplus or Sealing Machine KS-PO medplus

Blister types



Face seal blister



Trapped blister/wallet



Blister with lid material from roll

Time-tested technology: with a high number of cycles for large batches

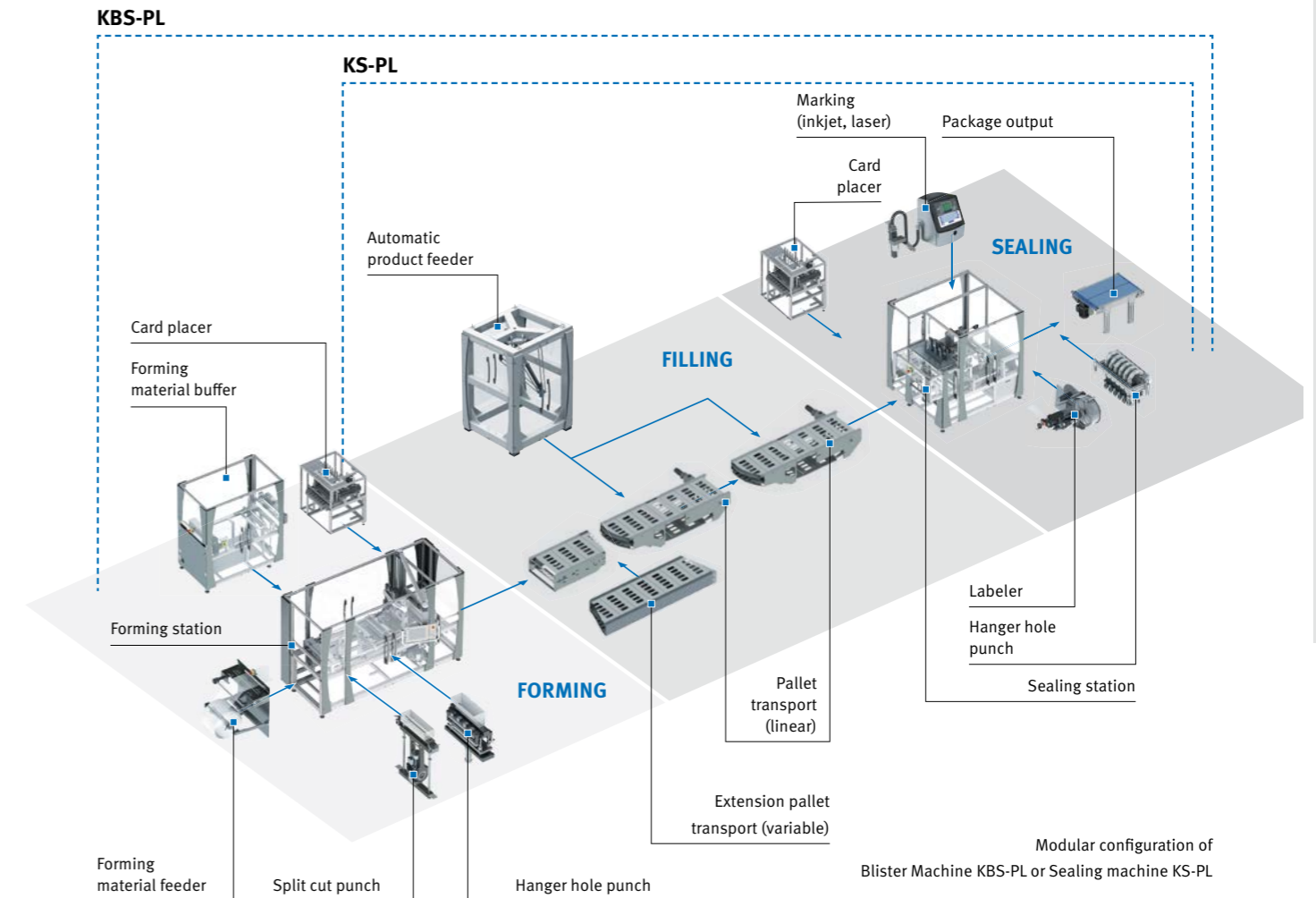
Sealing Machine KS-PL and Blister Machine KBS-PL
with linear pallet transport



The Sealing Machine KS-PL and the Blister Machine KBS-PL with linear pallet transport stand for the productive packaging of large batches of the same or similar products and the reliable processing of all standard rigid forming materials. Characteristic of both machines are the large format and sealing area – suitable, for example, for large-format, stand-up blisters or hanging blisters with a standard hanger hole – as well as the pallet section, which can be served manually or by a KOCH robot handling system. The user-friendly, clear-cut design allows full control of the packaging process at all times.

A large number of medical devices can be packaged on the two machines, either in face seal blisters or wallets. Furthermore, both the KBS-PL and the KS-PL are suitable for secondary packaging under cleanroom conditions.

Blister Machine KBS-PL – for the highly efficient packaging of blisters made of PVC, PET, or other rigid materials using proven technology



Modular configuration of Blister Machine KBS-PL or Sealing machine KS-PL



Thermal sealing station



Bronchial drops in a face seal blister

Technical data

- **Forming area:** 250 x 500 mm
- **Forming depth:** 67 mm
- **Sealing format:** 238 x 580 mm
- **Output:** 20 cycles/min., depending on forming material, blister shape/size, and sealing duration

Benefits

- Modular line concept with numerous integration and extension options
- Very high cycle rate
- Clear-cut, robust machine design
- For the forming and sealing of clamshells: line combination KB-KF and KS-PL

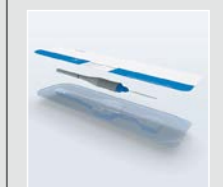
Blister types



Face seal blister



Trapped blister/wallet



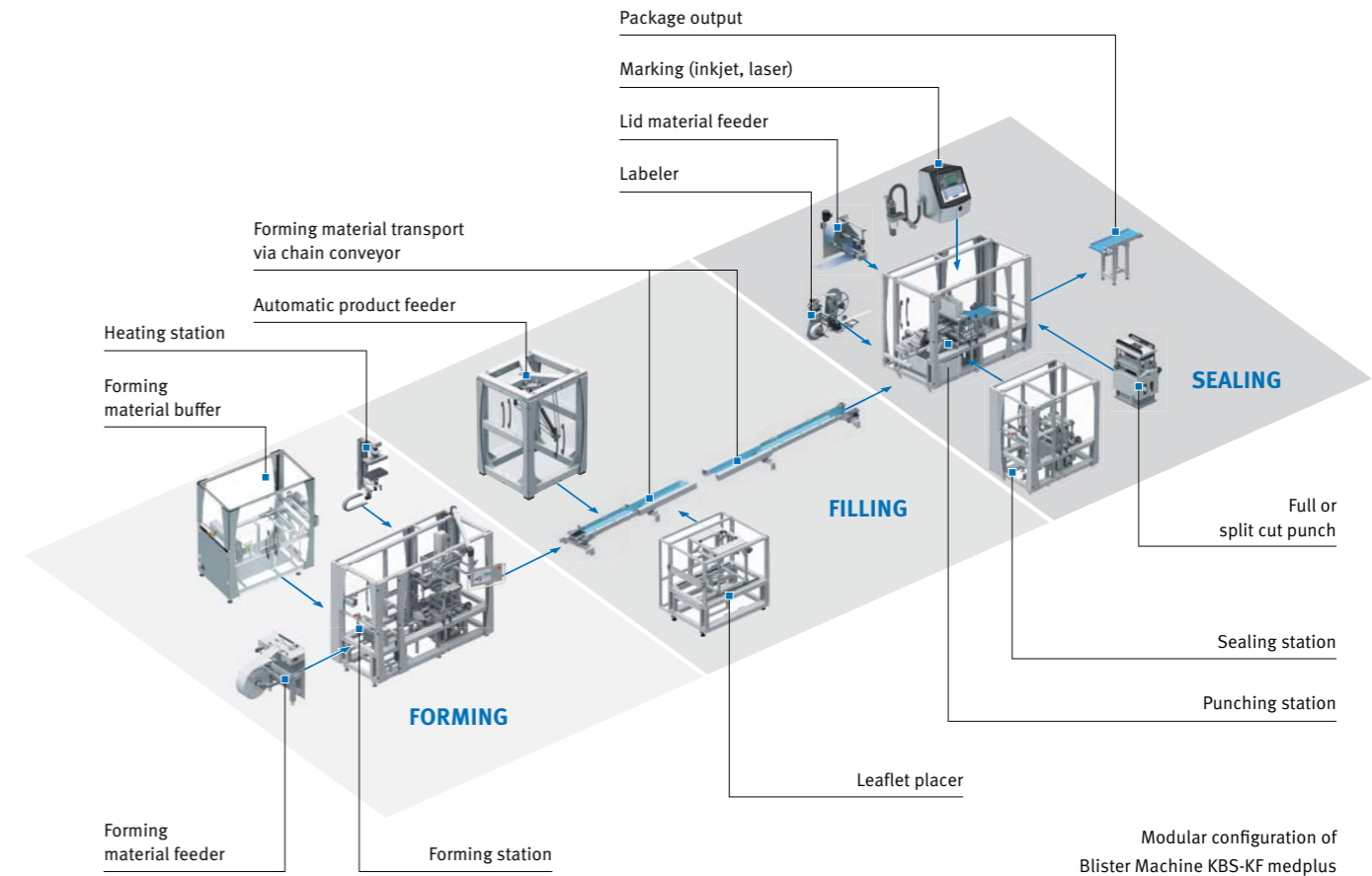
Blister with lid material from roll (only with KS-PL)

Functional reliability: for large formats and a variety of forming materials

Blister Machine KBS-KF medplus with chain conveyor



Exemplary version of Blister Machine KBS-KF medplus with lid material from the roll



KBS-KF medplus

- **Technical data**
- **Forming area:** from 150 x 300 mm to 500 x 500 mm
- **Forming depth:** 70 mm
- **Sealing format:** from 150 x 300 mm to 500 x 500 mm
- **Output:** 30 cycles/min., depending on forming material, blister shape/size, and sealing duration
- **Benefits**
- Very high cycle rate
- Processing of all standard types of forming material
- Low-cost format parts, no pallets or tool carriers required
- Fast format changeovers
- For the forming and sealing of clamshells: line combination with KB-KF and KS-PL



Chain transport with forming station

Multipart sterile filter housing with tube and cable set in blister sealed with Tyvek®



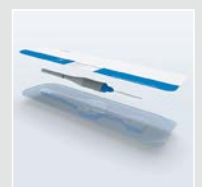
Whether flexible blisters sealed with Tyvek® or eco-friendly, all-PET blisters with an inserted card; whether sealed, as a clamshell, or a blister with lid material from the roll to allow easy product removal and reclosing: the Blister Machine KBS-KF medplus ensures high output for a wide variety of products – also under cleanroom conditions. The large forming and sealing format as well as a maximum forming depth of 70 mm permit the processing of individual, bulky products or multipart sets. The sealing technology is optimally attuned to the lid material – foils, Tyvek®, or aluminum. The robust, smooth-running chain conveyor guarantees reliable, accurate product transfer from station to station, as well as maximum machine uptime.

To ensure one hundred percent quality control and traceability in accordance with UDI or tracking and tracing specifications, the machine can be fitted with appropriate inspection and printing systems – as is the case with all machines and lines in the medplus version.

Blister types



Face seal blister



Blister with lid material from roll

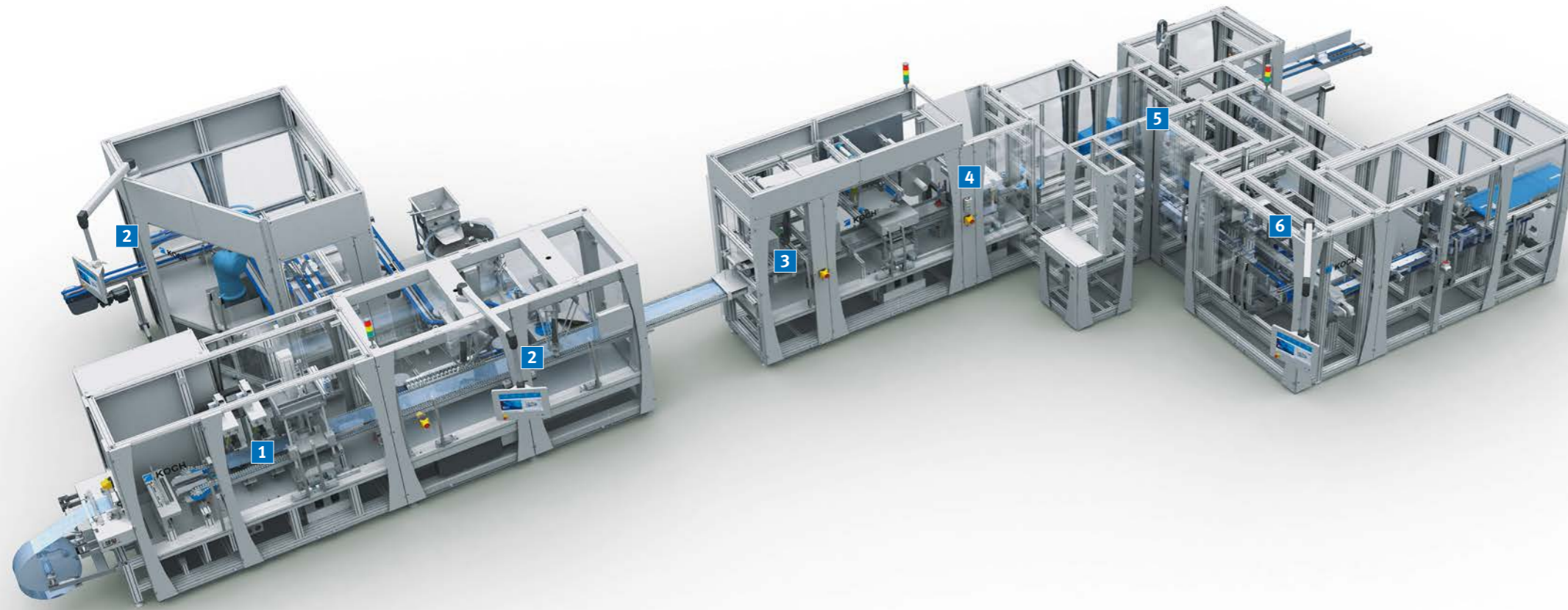


Blister to blister

A trade name for integrated, reliable, and highly flexible packaging

KOCHpackagingLine medplus

KOCH
packagingLine medplus



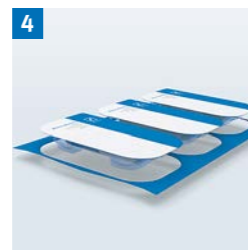
Forming



Product handling (filling)



Sealing



Punching



Grouping



End-of-line packaging

- **Line competence**
- Individual product handling concept
- Space-saving grouping and further processing of the finished blisters
- Feeding, erecting, filling, and closing of cartons
- End-of-line packaging in display trays suitable for transport, or on user-friendly, flexible pallets
- Straightforward, reliable operation with a central IPC control system
- Optional: integration of additional components, e.g., for marking and inspection

Standardization as far as possible and customization as required: this is the principle of a KOCH packagingLine medplus. The highly automated line packages flexibly and efficiently, and is optimally attuned to the packaging requirements of sensitive products. Fast, straightforward format changeovers ensure maximum machine uptime, while the well-devised concept allows the processing of small- as well as large-format products ranging from a single needle to an artificial knee joint. It is also possible to incorporate various packaging formats in a universal pack – for optimized storage and logistics, as well as easier intermediate or retail handling.

The basic version of a KOCH packagingLine medplus incorporates four perfectly synchronized components: a blister machine, a product feeder, a blister grouping module, and end-of-line packaging. Fully automated product feeding is possible using the Delta Robot KRH-D. We also integrate inline marking and inspection systems as required in compliance with UDI or tracking and tracing specifications. Straightforward, reliable operation is ensured by incorporating all components, including those from other manufacturers, in a seamless, end-to-end IPC control system.

Guaranteed process quality – from a single source

Every stage of a KOCH packagingLine medplus is competently managed by our experts. Concept and feasibility studies are as equally important as assistance in developing the pack design, or linking to ERP/MES systems, or existing SCADA control systems.

As your partner, we assume responsibility for the entire project and offer a turnkey service from a single source. Included are documentation, qualification, and all support services for long-term, smooth operation of your KOCH packagingLine medplus.

Guaranteed: a transparent supply chain, reliable from start to finish

Marking and inspection in compliance with UDI requirements

Standardized and unique marking for seamless traceability and to protect against counterfeits: these are the objectives of the UDI (Unique Device Identification) system for medical devices. UDI legislation stipulates the requirements and applies worldwide. A UDI system involves three elements: device and production identifiers (UDI data), data carriers, i.e. the product and packaging (UDI device), and the global UDI database.

Our experts have already implemented numerous UDI-compliant projects. They help you to apply the requirements, and those of tracking and tracing in the case of pharmaceutical products, to your packaging process. In addition to the integration of marking and inspection systems, interface management for data transfer to higher-ranking systems plays an important role. The benefits of a UDI system using automated data acquisition are also to be considered in the course of consultation with us.

Examples of medplus packaging expertise in all risk classes

Class I	Class IIa	Class IIb	Class III
			
<p>Surgical instruments</p> <ul style="list-style-type: none"> ■ Medical instruments ■ Dressing material 	<p>Disposable syringes</p> <ul style="list-style-type: none"> ■ Dental inlays ■ Contact lenses ■ Disposable syringes 	<p>Inhalation system</p> <ul style="list-style-type: none"> ■ Respirators ■ Dialysis devices ■ Condoms ■ Cleaning solutions for contact lenses ■ Dental implants 	<p>Artificial knee joint</p> <ul style="list-style-type: none"> ■ Cardiovascular and neurological catheters ■ Coronary stents, cardiac valves, cardiac pacemakers ■ Absorbable suture material ■ Breast implants

Inline: marking in perfect quality

All packaging units, from the smallest to the largest, have to be marked in compliance with UDI or tracking and tracing specifications. We select the appropriate printing systems and integrate them into the blister machine or packaging line. All relevant data such as the manufacturer's identification, product reference code, batch number, serial number, and production date are applied inline in the correct combination and quality.

- **Integrated as required: inline systems**
 - Thermal inkjet printing system
 - Continuous inkjet printing system
 - Thermal transfer systems
 - Laser marking systems
 - Labeler with/without marking system
 - Drop-on-demand marking systems
 - Braille marking systems



Thermal inkjet printing system with four print heads for the marking of blister cards

Print Machine KPM-200 for the flexible, offline marking of different carrier materials with serialization data as well as other information



Maximum flexibility: offline marking with the KPM-200

Our Print Machine KPM-200 offers a GMP-compliant, offline marking solution allowing seamless connection to your SCADA or ERP system. On account of its high speed and capacity to mark a wide variety of products, the KPM-200 is suitable for constant use at one packaging line or can cover the needs of several lines. Format adjustments are quick and easy as no parts have to be exchanged. Operation is via a user-friendly touchscreen. The KPM-200 can be fitted with every standard printing system and, if required, can be extended by a product positioning and grouping system at the product discharge conveyor.

Documented: top process and packaging quality

Qualification from the machine design to acceptance

A safely manufactured medical device demands perfect results from all processes, including the packaging itself. Full functionality must be documented. We execute the operational, hardware, and software design according to your specifications. Our experts ensure detailed documentation covering design qualification, the risk analysis of relevant process steps, the factory acceptance test, the SAT, and subsequent installation and operational qualification. We supply all required documents for machines and follow-up orders according to your wishes and in compliance with EU or FDA (GMP/GAMP5) specifications.

- **Nothing is missed**
- Quality and integrity of the pack contents
- Positioning and printing of the label
- Presence and readability of variable product data (OCV, OCR), i.e., bar code, data matrix code, etc.
- Visual packaging quality
- Individual packaging specifications



Exemplary marking and inspection system that prints and subsequently verifies variable product data

High-end monitoring in real time: inspection modules

One hundred percent quality control during the ongoing process with maximum precision at high speeds: we provide a selection of systems for contact-free, visual inspection. These can be integrated at the relevant positions of the packaging process: for example, to check product presence or alignment during robot feeding, to verify product data and print images during marking, or to make a final inspection at the machine output. The acquired data is transmitted to the machine control system or to the next station of the process – for end-to-end reliability when packaging medical devices.



Machine qualification as required by the customer

- **KOCH qualification service from start to finish**
- Design qualification
- Qualification planning
- Functional design specification (FDS)
- Technical specification (TS)
- GMP risk analysis report
- Installation qualification (IQ) including cross-checking of the machine at KOCH
- Operational qualification (OQ) including cross-checking of the machine at KOCH
- Traceability matrix

Faster, better, easier, and more convenient: in short K 4.0

Digitalization services in special machine manufacturing

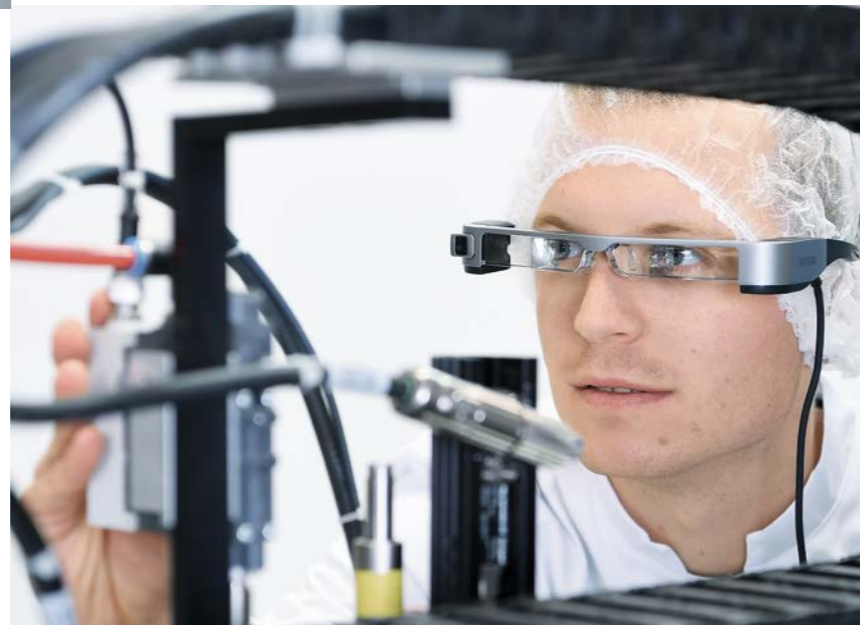
Networked, digital manufacturing means a number of benefits: more efficient processes, reduced costs, and increased machine availability. We are applying these advantages to special machine manufacturing: under the name K 4.0. We have developed a portfolio covering tailored digital solutions that complement our core skills – the construction of individual blister machines and packaging lines. Services that make your day-to-day packaging processes easier, allow prompt support, and save time and costs.



SparePartsManager for the ordering of spare parts, also from mobile devices

Smart support worldwide: service glasses

Service glasses permit direct, immediate support at the machine when an on-site visit can be avoided. A secure voice and live image connection links one of our experts to your operator so he can be led through preventive maintenance measures or rectify a malfunction. The advantages here are obvious: reduced outlay for support, fewer on-site visits, and significantly increased machine uptime resulting from the global support of our services specialists.



Service glasses enable an experienced technician to look through the eyes of the operator to help him diagnose and rectify a malfunction



- **The new K 4.0 digital services portfolio**
- Service glasses for location-independent, interactive support
- SparePartsManager for the online ordering of spare parts for each individual machine configuration
- HMI panel with web-server technology for straightforward setups and operation
- Smart app to access production data
- Virtual commissioning for optimized engineering quality

Online ordering of spare parts: the SparePartsManager

A first in special machine manufacturing: the ordering of spare, wearing, and format parts for your specific machine configuration with just a few clicks. Navigation through the catalog – available both online and offline – is uncomplicated. Drawings and 2D models assist fast identification of the required parts. Assembly drawings are available for every machine, and the integration of additional information and files is possible.

Intuitively correct operation: the HMI panel

The optics of a tablet, 21" monitor, graphical switch panel, and clear images of all relevant machine views and parameters: the HMI panel permits intuitively correct operation and fast setups – directly at the machine or via a mobile device.

Faster commissioning – using a virtual model

Another K 4.0 solution is virtual commissioning using 3D machine simulation and original software. It speeds up the commissioning of your machine or line, and your personnel can be trained using the virtual model. When upgrades are required, the machine can continue operation while one or various retrofit options are simulated virtually prior to deciding on the best solution for the actual upgrade.



KOCH Pac-Systeme: reliable partner for innovative machine technology and services

Medium-sized company geared to international business

We have been catering to the needs of customers with our machine technology and services for over four decades. While recording sound growth, and systematically expanding our portfolio, we remain faithful to the characteristic assets of a medium-sized company: a high level of flexibility in response to your requirements, short communication channels, and personal contact.

Linchpin when it comes to developing, planning, and building customized machines and lines are the people, over 300 qualified members of staff, many trained internally, who work for KOCH. They help attain the best possible quality, pass on their know-how, and ensure that we continue to be a reliable partner for you in the future.

Personal contacts, professional advice – worldwide

Our understanding of customer care is truly representative of a medium-sized company: a personal contact is in your vicinity. In addition to our headquarters in Pfalzgrafenweiler, we have offices in France, China, Singapore, India, and the USA. Furthermore, we have international sales partners throughout the world. Everyone everywhere, is well aware of what is important to you – productive packaging at its best.

Added expertise as a member of the Uhlmann Group

As a member company of the Uhlmann Group, we have good connections with the experts in Laupheim. We can make use of the in-depth expertise of Uhlmann Pac-Systeme when it comes to pharmaceutical packaging.



■ Global presence

- Headquarters and manufacturing facilities in Pfalzgrafenweiler, Germany
- Offices in France, China, Singapore, India, and the USA
- Sales partners worldwide
- Integration into the international sales network of Uhlmann Pac-Systeme
- Prompt assistance worldwide via online support or the service hotline +49 7445 181-181
- For more information please visit www.koch-pac-systeme.com



KOCH Support + Services:

solutions for highly productive packaging

The name KOCH Support + Services stands for a comprehensive, modularly structured portfolio, with which we accompany you over the entire service life of your machine – with a services package perfectly tailored to your machine and your production environment. All fields are covered: installation and commissioning, machine availability, format and spare parts, automation and integration, technical support, and KOCH training.



www.koch-pac-systeme.com

KOCH Pac-Systeme GmbH
Dieselstrasse 13
72285 Pfalzgrafenweiler • Germany
Phone +49 7445 181-0
Fax +49 7445 181-50
info@koch-pac-systeme.com

Member of the Uhlmann Group