

# SMART SOLUTIONS FOR PHARMA EXPERTS SYRINGE & CARTRIDGE FILLING EXPERTISE

Member of

PACKAGING VALLEY

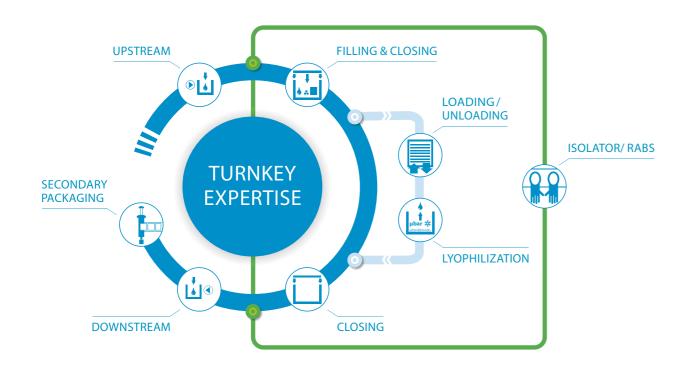
Germany

#### **OPTIMA**

#### For uncompromising pharmaceutical applications

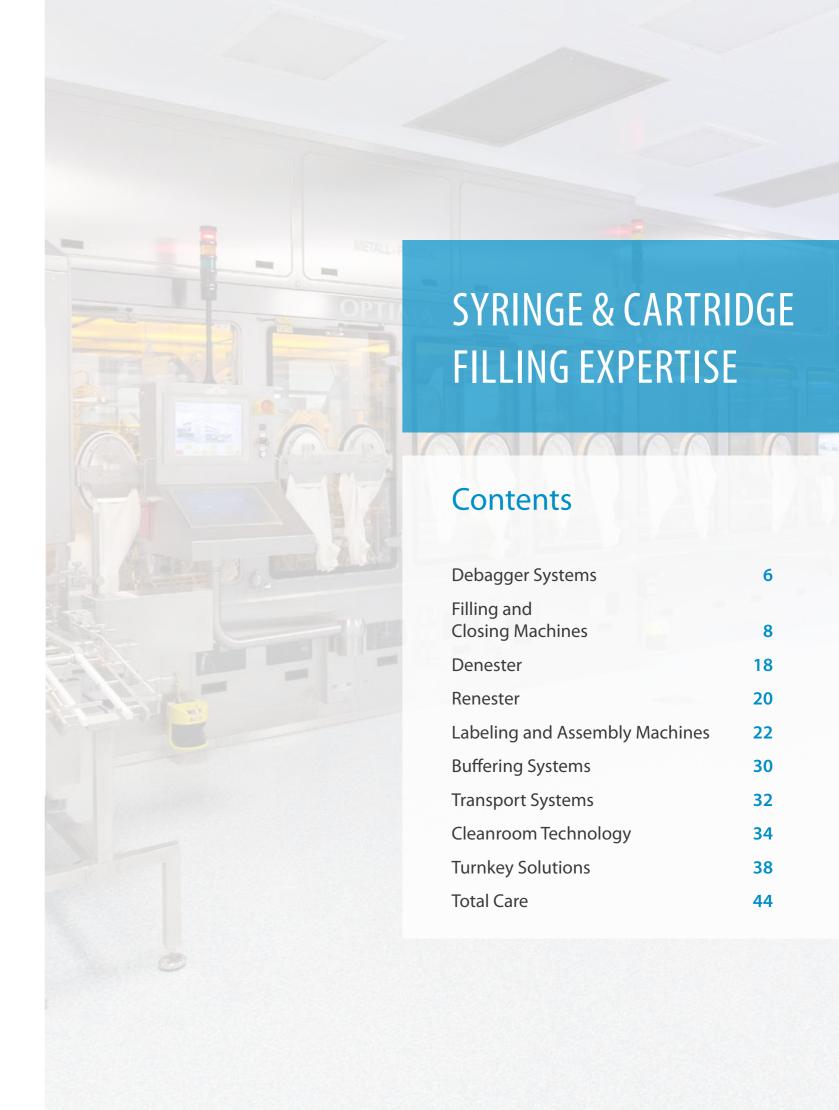
Optima Pharma develops and manufactures highly flexible filling, closing and process technology for pharmaceutical products. Exceedingly sophisticated, fully automated systems from Optima Pharma are used to process blood plasma products, vaccines, oncology and biotech products in prefilled syringes, vials, bottles and cartridges. Non-sterile pharmaceu-

ticals and diagnostics are additional applications of Optima Pharma. The company's extensive technology portfolio includes washing machines, sterilization tunnels, filling and sealing, robotic product handling and other functions. Freeze drying systems and isolator technologies complete the extensive turnkey systems by Optima Pharma.



#### OPTIMA packaging group GmbH







DBA-SBA

Fully-automatic

inner bag

DBA

Fully-automatic

bag debagger



# Select the Appropriate **Opening System**

#### **DBM**

Manual system facilitates the opening of the bags using gloves.

#### **DBS**

Semi-automatic system with manual bag opening using gloves. The bags are fed either manually or automatically to the debagger. They are then opened semi-automatically and disposed of.

#### DBA

The bags are automatically fed and opened and the tub is automatically removed from the opened bag. The bag is then remove automatically.

#### **TRB**

System for the manual opening of bags with gloves.

#### **TRR**

Fully-automatic cleanroom suitable robot system for the Tyvek® lid and liner removal. The syringe handling robot is specifically designed for cleanroom applications. The handling robot peels off the Tyvek cover from the tub, removes the Tyvek® liner and transports the tubs with a gripper.







# Process up to **Three Container Types**

#### SV125

With the SV125 it is possible to process three different container types on a single machine. The SV125 can be made to process nested syringes, vials and cartridges. It is also possible to integrate up to three different types of filling systems, such as a peristaltic, rotary pump and timepressure, to meet a broad range of product requirements. Filling and closing with a vacuum is another option that is available. Switching over from one container type to another is comparable to a conventional format change

The filler can be rounded out with tertiary equipment such as a debagger or Tyvek® lid and liner removal for full

With addional isolator technology the machine provides the highest levels of sterility.





#### Filling and **Closing Machines**

#### **Your Advantages**

- Output: up to 20,000 pcs./h
- Processing of three different container types possible: syringes, vials, cartridges
- Slim and compact design
- 2-10-laned dosing system
- High dosing accuracy
- Quick changeover time of format parts

- Vacuum filling and vacuum stopper insertion
- In-Process Control
- Pre- and post gas flushing
- Integration of all containment systems oRABS, cRABS and isolator



# **User Friendly** Operation, Easy Access and Reliability

#### H4-10

The filling and closing machine, model H4-10, meets your requirements for simple operation, accessibility, reliability and compact design. Nested syringes, vials and cartridges are all processed with this machine. Automated Tyvek® lid and liner removal can be integrated, if required. Space for the robot preplanned on the filling machine, thereby saving space. A 10-laned system is provided for filling. Rotary piston pumps as well as peristaltic or time pressure filling systems can be added at any time for filling flexibility and simple format changes. Regardless whether the system is an oRABS, cRABS or an isolator, all of our systems can be economically fitted to the standardized machine baseplate. The transport system ensures particularly careful handling of the containers. The same applies to the upgrading of In-Process Control, vacuum filling and vacuum stopper inserting.





#### Filling and **Closing Machines**

#### **Your Advantages**

- Output: up to 24,000 pcs./h
- High dosing accuracy with – rotary piston pump system – time pressure dosing system

– peristaltic pump system

- Processing of three different container types possible: syringes, vials, cartridges
- Small machine footprint
- Processing of liquid to highly viscous products
- Processing of highly potent and non highly potent products

- Vacuum filling and stopper inserting
- In-Process Control
- Pre- and post gas flushing
- Integration of all containment systems oRABS, cRABS and isolator



# One Machine to Process Nested Syringes, **Cartridges and Vials**

#### H6-10

With the H6-10 it is possible to process three different container types on a single machine. The machine is customized to process nested syringes, vials and cartridges.

It is also possible to integrate up to three different types of dosing systems, such as a peristaltic pumps, rotary piston pumps and a time pressure system; to meet a broad range of product requirements. Filling and closing with a vacuum as well as In-Process Control are further available options on this machine.





#### **Filling and Closing Machines**

#### **Your Advantages**

- Output: up to 36,000 pcs./h
- Highest dosing technique either with
- rotary piston pump system
- time pressure dosing system
- peristaltic pump system
- Processing of three different container types possible: syringes, vials, cartridges
- Linear and vertical processing of
- Linear transport system allows the combination of the H6-10 with other machinery
- Processing of highly potent and non highly potent products

- Vacuum filling and stopper inserting
- In-Process Control
- Integration of all containment systems oRABS, cRABS and isolator



## **Take Your Production** to the Highest Performance Level

#### H10-16

A fully-automatic filling and closing machine to process disposable, commercially available nested syringes. With a format range up to 50 ml and an output of up to 60,000 syringes/hour can be reached with the 16-lane version. The machine is equipped with an infeed and a discharge conveyor belt for the tubs.





#### Filling and **Closing Machines**

- Output: up to 60,000 pcs./h
- Highest dosing technique either with

– peristaltic pump system

- rotary piston pump system - time pressure dosing system
- Slim design

- Processing of three different container types possible: syringes, vials, cartridges
- Processing of liquid to highly viscous products
- Processing of highly potent and non highly potent products

- Vacuum filling and stopper inserting
- 100% In-Process Control
- Integration of all containment systems like oRABS, cRABS and isolators





UJ150

6-laned

up to

9,000 pcs./h

**RABS** version

UJ300

12-laned

up to

18,000 pcs./h



# Disposable Syringes -Filling with Hardly **Any Format Parts**

#### UniJect™

The UniJect™ "Prefill Injection Device" is a cost efficient, non-reusable and high quality injection unit for intramuscular and subcutaneous applications. The UniJect™ model guarantees a safe operation process, flexibility, a compact design and combines these features with a high output – the UJ120, UJ150 and UJ300. With the UniJect™ model almost no extra parts are required to process any UniJect™ devices. The UniJect™ devices are smoothly processed with an unwinding and rewinding device in a custom designed transport system. The filling station of the UniJect™ is designed for different filling systems: time pressure, rotary piston pumps or peristaltic pumps. This allows a variety of media to be processed. Programmable fill movements provide an optimal output and the parameters of different products and filling volumes are set simply by using a teach-in function. The UniJect™ devices are sealed with a heat sealing module. Process data, like time, temperature and pressure are continuously monitored and adjusted for optimum results.







## Select the Right **Denester to Meet Your Production Needs**

#### SH

The aseptically filled and stoppered syringes are automatically removed from the nest and placed into a discharge track. The tub can be placed manually or automatically onto the infeed conveyor of the machine. The following process is fully automated. The empty nest is transported with an intermittent conveyor belt to the stacking device and automatically stacked then the tubs and nests in the stack are manually removed. The machine discharge can be one or two lanes.

#### TD

The syringes are automatically removed from the tray and placed onto a discharge track. The Rondotray stacks are manually placed on the infeed conveyor belt of the machine. The following process is fully automated; the Rondo trays are automatically destacked and each tray is transported past the removal station using a carrier device, finally, the syringes are removed into a discharge track. The empty Rondo trays are automatically stacked and transported onto a discharge conveyor belt.





SN260

3-laned

up to 36,000 pcs./h

TR240

up to 24,000 pcs./h



# **Newly Defined Syringe Handling**

#### SN

The completely processed syringes can be manually or automatically inserted into the nests. The syringes are fed, single-lane, into an oval transport system and are spaced out respectively to fit the arrangement of the syringe nest. For single-lane nest transport, the oval stops to take out a row of format dependent syringes with a vacuum. For the two and three lane nest transport, 2 or 3 grippers take out one row of syringes from the continuously running oval transport. The grippers work independently and the syringes are inserted in separately centered nests.

#### TR

Using the fully-automatic renester, the syringes, which are fed with the aid of a feeding track and infeed wheels, are inserted into Rondo trays. The empty Rondo tray stacks are manually placed onto the infeed conveyor belt and the Rondo trays are automatically destacked. Each Rondo tray is transported past the inserting station with a carrier device and the syringes are inserted into the Rondo trays. The filled Rondo trays are automatically stacked and transported onto the discharge conveyor belt.









# Continuous and Intermittent Operating Labeling and **Assembling Machine**

#### EKK62

An economical, compact solution for medium and large batches, this machine processes all common glass and plastic syringes ranging from 0.5 to 20 ml. The syringes are transported into the continuous motion transport star-wheel using an inclined infeed and an infeed wheel. At the labelling station, the syringes are rotated using a roller band and the labels are glued on. A camera detects the presence of the label, on the label dispenser, a second camera controls the correct print of the label. Then, the syringes are distributed with two vacuum wheels into the discharge/reject.







# **Compact Designed Labeling and Plunger Rod Inserting Machine**

#### **EKM**

Three functions integrated into one machine. The machine is designed to assemble finger flanges, insert plunger rods and label all common glass and plastic syringes. This machine processes syringes from 0.5 to 20 ml.

#### EK/CM

Labelling, plunger rod insertion and backstop assembly all combined into one machine. This machine is the economical, compact solution for small batches. It processes all common glass and plastic syringes from 0.5 to 10 ml.







# Continuous or Intermittent Operating **Backstop Assembly** Machine

#### CM4/CM12/CM18

The working principle is either intermittent (CM4) or continuous motion (CM18). The syringes are directly fed into the machine with a chute to guide the syringes directly into the infeed star-wheel. While transferring the syringes from the transfer star-wheel into the main star-wheel, the back stops are assembled onto the finger flange of the syringe. The sorting/orientation of the backstops is done using a sorting bowl, the backstops are transported onto a rail to the point of assembly and the assembled syringes are guided out of the main star-wheel for further proces-

CM4: The fully assembled syringe is pushed laterally out of the star-wheel into the discharge chute.

CM18: The fully assembled syringe is pushed tangentially into the discharge star-wheel.





CM4/

CM12/

CM18

Backstop

0.5 ml - 10

up to

EKCS

Labeling and

plunger rod in-

sertion machine

with safety device

and finger flange

up to

3,600 pcs./h

VSM1800

0.5 ml - 20 ml

18,000 pcs./h

VSM2400

24,000 pcs./h

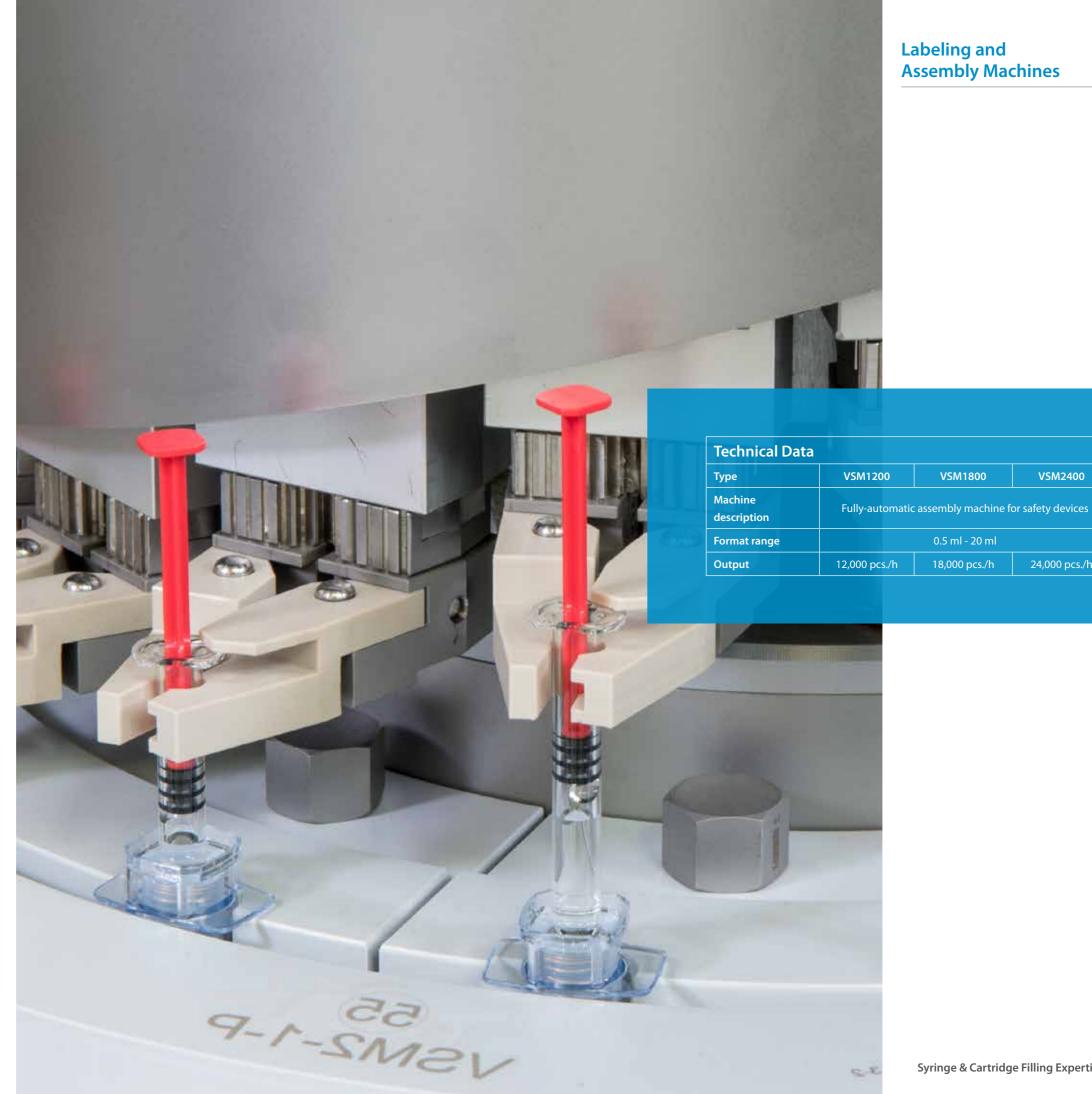


# Be on the Safe Side -**Appropriate Safety Device Assembly Machines**

#### **VSM**

The safety devices are fed into the machine using an infeed chute. Depending on the product, they are carried over by a single or double scroll, separated and fed to the first labelling star-wheel. The label dispenser can be equipped with different print and control systems, depending on the customer's requests. Then, the safety devices are transported to the assembly star-wheel. The syringes are also fed into the machine using an infeed chute and are separated using an infeed wheel. The camcontrolled grippers pick up the syringes and insert them into the devices. Then, the safety devices are transported to the insertion star-wheel. The syringes and plungers are completely pushed into the devices. To ensure the exact insertion of the syringes, they are centered in the star-wheel with grippers. Then, the syringes are fed using two vacuum wheels to the discharge or reject stations. Manual safety device systems are available upon request.







SP900

up to

300 pcs.

SP2000/3000

up to

300 pcs.



# **Select Your Buffering System**

#### SP300/600/900

Syringes are fed into a tray loading system using a starwheel. The tray is filled row by row. The nest moves perpendicular to the infeed, with the row in front of the infeed being filled before shifting to the next row. The individual lanes are filled and emptied with gravity that is controlled with a discharge finger and an accumulation sensor.

#### SP2000/3000

Syringe accumulation buffer using the first-in, first-out principle, the syringes are fed into the accumulation racks with gravity or are pushed in and out of the rack mechanically. Empty racks descend below the machine plate and cycle back to the infeed.









# Syringe Transport System for Your Requirements

#### STS

The syringe transport system can be utilized as an infeed or discharge conveyor belt. Furthermore, it can be used to connect individual machines. Differences in height can be compensated for with an infinitely adjustable crossing angle.

#### **TVB**

The paternoster system was developed for the optimization of complete turnkey lines to provide operators a passageway under the tub transport. The paternoster is available in various designs and sizes.







# Cleanroom Technology for the Highest **Aseptic Quality**

A leading global company for the development, manufacturing, installation and validation of isolators. Metall+Plastic isolators can be installed on different pharmaceutical machinery and combined with various process functions, such as machines for the aseptic dosing of liquids and powder, epyrogenation tunnels, freeze dryers, autoclaving equipment and aseptic transfer systems. Metall+Plastic also designs e-beam tunnels and emitter, locks, gas tight doors and glove testing systems.

### **Triple Protection**

At first glance, all three systems work as a clean room micro plant. As far as technology and regulation are concerned, the differences are quite considerable and have to be assessed for each individual project. We would be happy to recommend the correct protection system that is suitable for your application.

To restrict the operator access to the process area, our filling machines can be provided with RABS equipment as an option. The restricted access is, in this case, achieved by glove systems and mock-up studies are used to determine the gloves' positions in advance.





#### **Closed Restricted AccessBarrier System** (C-RABS)

The technical module consists of high-quality stainless steel materials and is located above the protection module. It contains the complete technical air equipment, such as ventilators, filters, cleanroom illumination and air distribution diaphragm.

The protection module consists of high-quality stainless steel materials. Doors, windows and other functional elements are integrated into the modular sectional framework. Intervention in the protection module is achieved with glove accesses that are integrated into the glass doors (tempered safety glass (ESG).





# State-of-the-Art Technology for Economical and Reliable Decontamination

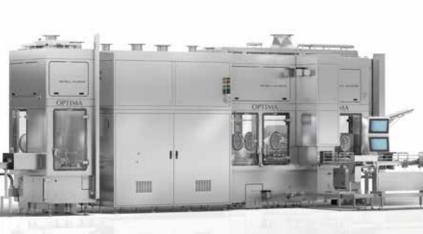
#### E-BEAM

The application of pre-sterilized containers in tubs gains more and more importance due to its reliability and efficiency.

The Metall+Plastic E-Beam tunnel E-BEAMflex guarantees an average radiation energy of a minimum of 25kGy of the surface decontamination of pre-sterilized tubs. The E-Beam was designed for the continuous, lowmaintenance aseptic transfer in class D/C room for class A-filling lines. The E-BEAMflex is qualified and validated as a unit.

#### **Your Requirements:**

- Surface decontamination pre-sterilized, nested tubs
- Safe and continuous aseptic transfer of tubes in the
- Low-maintenance and stable tub transport process in the filling line
- Time savings during qualification and validation, FDA and audit conform





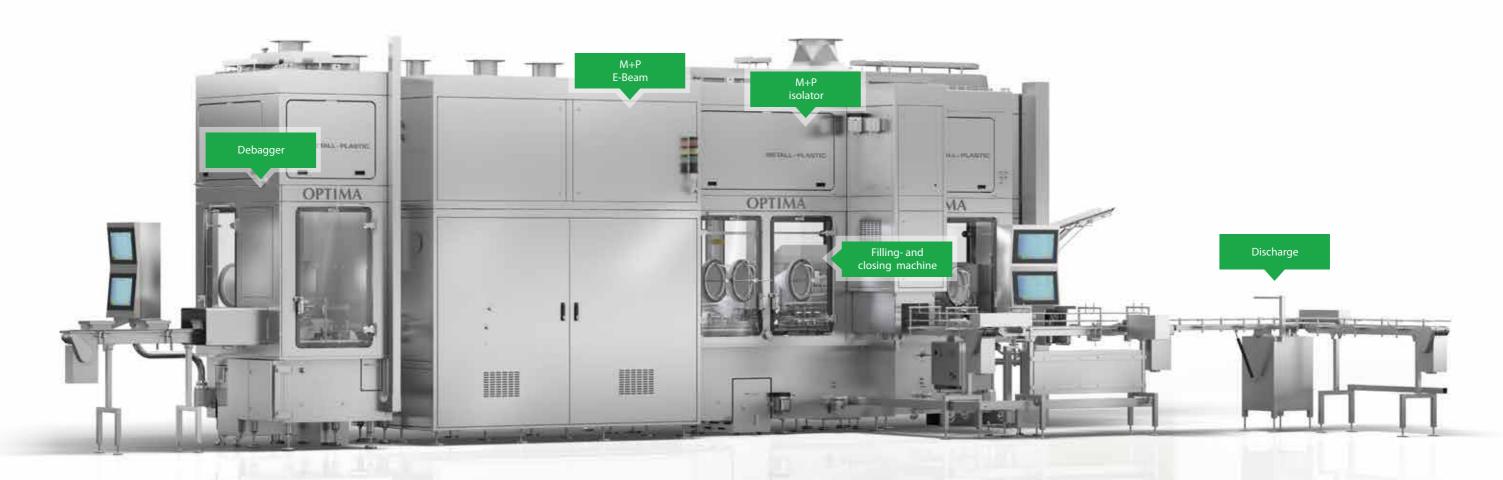
#### **Your Advantages**

- All common tub sizes can be processed, also transparent tubs
- Compact design for small spaces
- 100% in-house production ensures highest quality and flexibility
- Easy access for cleaning and maintenance
- Safe radiation protection due to rotary drums without unnecessary closing sensors
- Monitoring of tubs also in the radiation area



# **Turnkey Line for Nested Syringes**

DBA | M+P E-Beam | TRR130 | SV125-10 | M+P Isolator



### **Technical Data**

- Output: up to 20,000 pcs./h
- Filling stations: up to 10-laned
- Processing range carpules: 3 ml 10 ml
- Processing range syringes: 0.5 ml 50 ml
- Processing range vials: 0.5 ml 50 ml

### **Features**

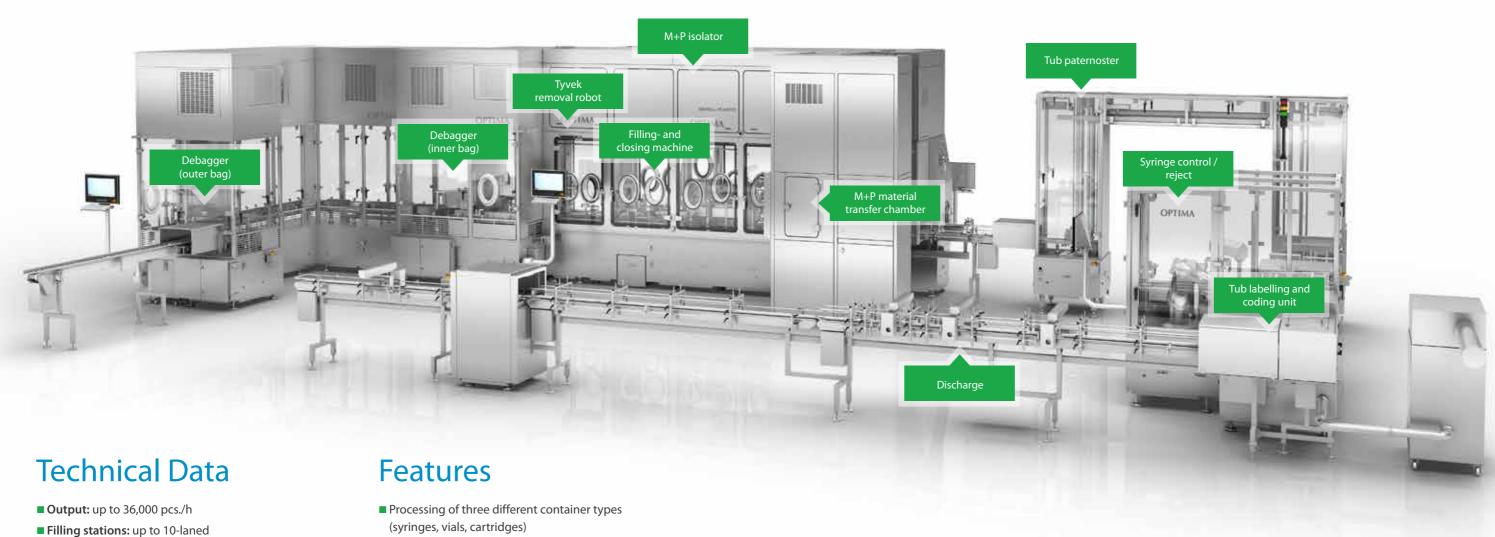
- Processing of three different container types (syringes, vials, cartridges)
- Vacuum filling and vacuum stopper insertion
- Fully automatic In-Process Control
- Processing from liquid to highly viscous products, from non highly potent to highly potent products
- Suitable for oRABS, cRABS and Isolator

38 | OPTIMA pharma Syringe & Cartridge Filling Expertise | 39



# Turnkey-Linie for Nested Syringes

DBA-S, DBA-SBA, TRR130, H6-10, TVB, SIRM, M+P Isolator



- Processing range carpules: 3 ml 20 ml
- Processing range syringes: 0.5 ml 20 ml
- Processing range vials: 0.5 ml 30 ml

- Vacuum filling and vacuum stopper insertion
- Fully automatic In-Process Control
- Processing from liquid to highly viscous products, from non highly potent to highly potent products
- Suitable for oRABS, cRABS and Isolator

40 | OPTIMA pharma Syringe & Cartridge Filling Expertise | 41



# Turnkey-Linie for Nested Syringes

DBS | DBA | TRR130 | SV125 | SH120 | CM12/EKK62



42 | OPTIMA pharma

Syringe & Cartridge Filling Expertise | 43



# Life Cycle **Based Services**

Packaging processes of the future will be more efficient, digitally interconnected and complex. We gladly support you with this process. Personal and individual customer service is the highest priority at Optima. Choose from our comprehensive "OPTIMA Total Care" portfolio to support your needs and to reach your objectives faster and more efficiently. Our consultants and experts will be at your side at all times during the complete life cycle of your equipment. Our constant focus: Your needs, your objectives and your success. You can rely on us.

#### **Smart Services**

Our Smart Services are designed to effectively complement our Basic Services package. They include all of Optima's digital services, which you use to improve the efficiency of your production. These Services comprise Knowledge Transfer, Manufacturing Intelligence, Maintenance Support, and Smart Assistance. What you get is a powerful comprehensive package that can be tailored precisely to your requirements, including everything from OEE optimization to your desired maintenance mode and fast access to machine knowledge, as well as digital support when process issues or format changes occur. All services are available around the clock on the Optima central platform. In addition, they can also be tested live at the Digital Innovation Center in Schwäbisch Hall.



#### **Basic Services**

services that are designed to support you in all qualification, and user training. Integrated market. They continue in the ramp-up phase, up to retrofitting.



→ More Information:

www.optima-packaging.com/totalcare



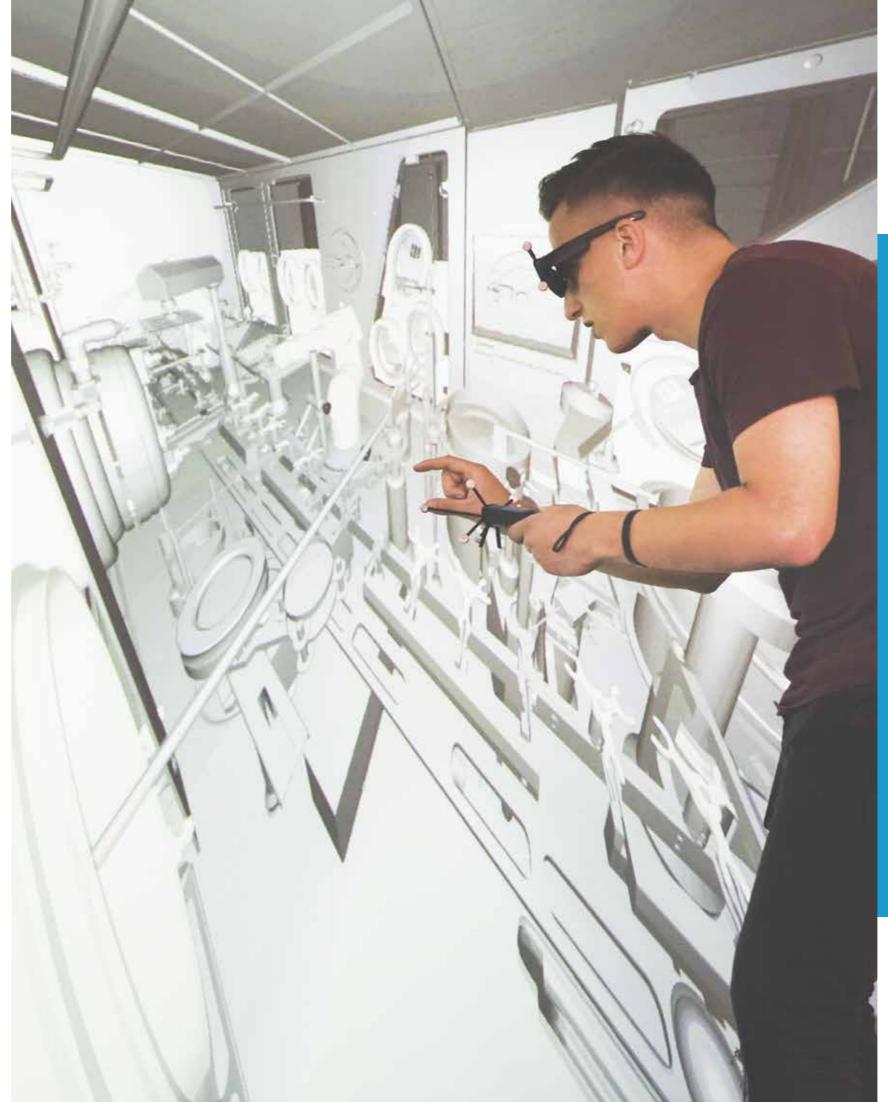


# **Instruction & Training**

Become an expert. Our specialists will convey their knowledge about Optima's equipment through virtual reality, at the machine at Optima's facility or at your production site. The easy and correct utilization of our machinery is our work guarantee. With each custom tailored machine, we offer individual training that is customized to your needs. A special emphasis is placed on complete documentation.

For basic or more extensive expert knowledge, you can chose from a variety of training units based on your requirements. After the training, you will be able to identify application opportunities, potential safety hazards, error sources and understand safety requirements.





#### **Your Advantages**

- Training tailored to your requirements and designed for your machine needs
- Minimal downtime, high efficiency and minimal error rate
- User-oriented machine settings
- Knowledge transfer through experts
- Production safety for operators

#### **Services**

- Virtual reality training
- Training units tailored to your needs
- Individual training documentation
- Various training medias as reference guides
- Basic and operator training
- Technician and expert training
- "Train-the-Trainer" education
- Safety training

www.optima-packaging.com/pharma