

**SYNTEGON**

PROCESSING & PACKAGING



# Pre-filled Syringes Portfolio. ▢

Pharma Liquid.

# About Syntegon

**Processing and packaging for a better life – this is what 5,800 Syntegon employees work for every day.**



Be it with individual machines, systems, or services, Syntegon helps its customers in the global pharmaceutical and food industries to improve people's lives. The company, which is headquartered in Waiblingen, Germany, looks back on more than 160 years of experience. In the pharma sector, the company's intelligent solutions enable the safe and high-quality production, processing, filling, inspection, and packaging of liquid and solid pharmaceuticals. In the food industry, Syntegon's flexible and reliable technologies produce and pack confectionery, dry food, frozen food, and dairy products. With 1,100 service experts and a comprehensive service portfolio throughout the entire machine lifecycle from spare parts management to digital line optimization, Syntegon lays the foundation for smooth production processes for all customers. More than 30 sites in almost 20 countries keep a firm eye on Syntegon's impact on the environment and society. Syntegon is a leader in the development of sustainable packaging solutions, reduces the energy consumption of its machines and pursues ambitious goals to lower its emissions.



# Global megatrends in the pharmaceutical industry.

Global population is growing by 80 million people per year.



01



Change in development pipelines: faster cycles with more products and less blockbusters for smaller patient groups, higher demand for individualized medicines. Quick reactions to changing market- and health needs (Covid-19).

02



Production of pharmaceuticals according to highest safety standards in a changing environment with increasing demands.

03



High requirements to minimize environmental pollution, especially of the entire CO<sub>2</sub> footprint over the machine lifetimes by reducing waste, media and energy consumption.

04



New therapies for chronic diseases, more patient data, digital solutions to create higher production transparencies.

05



Rising demand for cost-effective medicines in an increasingly competitive environment.

06



Increasing life expectancy, growing number of older people, higher demand for medication.





## ABO 5000 DB

The first fully automatic double bag opener – up to 6 tubs/min.

### BENEFITS

- Fully automatic arrangement/ preparation for cutting the inner bag by vacuum and tightening by rollers directly after double bag ABO
- Optimized transfer

## ABO 5000 No-Touch-Transfer (NTT)

Fully automatic machine for unpacking tubs for nested syringes, nested vials and nested cartridges – up to 6 tubs/min.

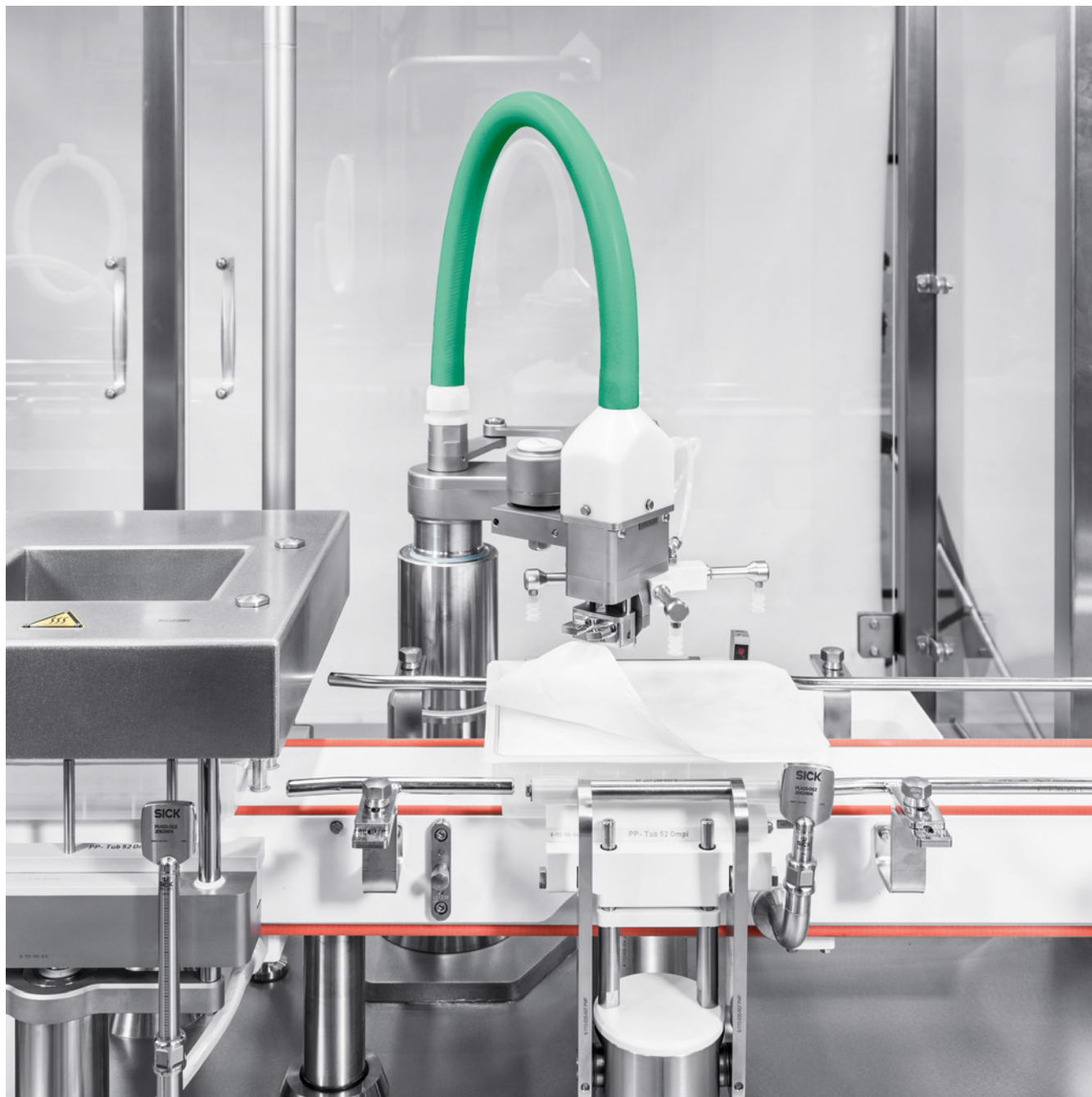
### BENEFITS

- Minimal contamination risk through the use of the bag's protective attributes
- Reliable handling of the bags with reproducible conditions
- Syntegon Integration Advantage: Safety of a single supplier (ABO as one part of an entire line)
- Clear separation of clean room areas
- No contact between the tub surface and outside of the bag
- Safe and reproducible separation of bag and tub
- Only one piece of waste

### OPTIONS

- Different infeed variations





# ATO 3000/5000

Fully automatic machine for lid and liner removal for nested syringes tubs, nested vials and nested cartridges – up to 6 tubs/min.

## BENEFITS

- Low particle risk through specific pre-heating and optimized motions for the removal and disposal of lid and liner
- Defined pre-processing of peeling off the lid safely
- Machine including robotics fit for Isolator installation

## OPTIONS

- Lid and liner verification

# Filling technologies for your applications.

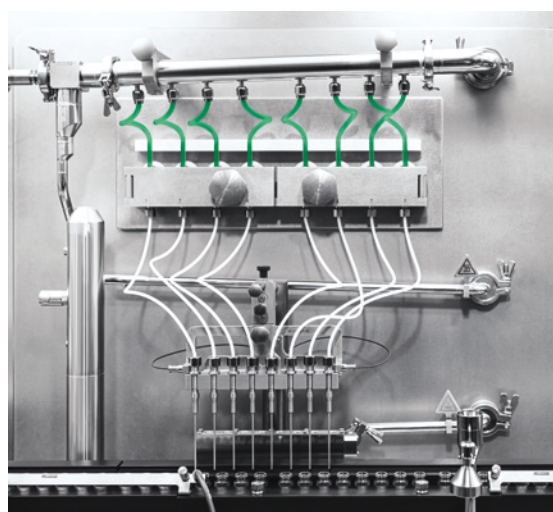


## Rotary valve piston pump

The proven filling technology, even for highly viscous filling materials, guarantees reliable and drip-free filling.

### BENEFITS

- Exactly repeatable filling volumes
- Easy to clean and sterilize
- No seals

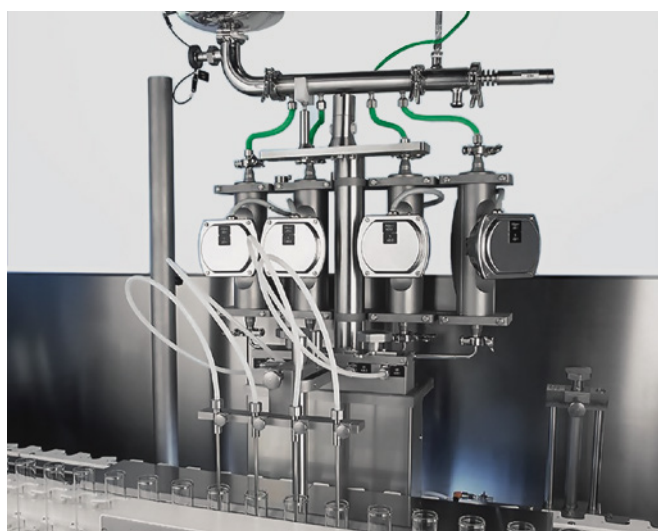


## Time pressure filling system

A high-precision filling system that enables maximum product volume usage.

### BENEFITS

- Easy cleaning
- Sealed system
- Best system for CIP/SIP

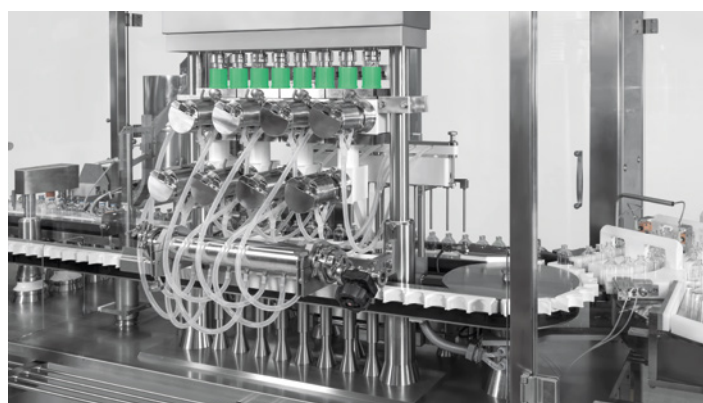


## Mass flow filling system

The filling system for special requirements with integrated indirect 100 % in-process control functionalities.

### BENEFITS

- No difficulties with crystallizing products
- Sealed system
- Complete emptying possible
- No particle generation



## Combi filling station

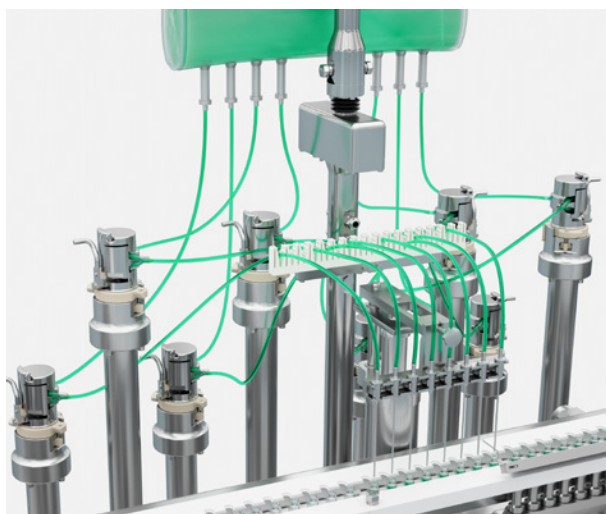
A highly flexible filling station with which multiple filling technologies can be used in one pharmaceutical filling machine.

### BENEFITS

- Same footprint as a normal filling station, no additional trolleys required for the operation of different filling systems
- Perfect solution for all product requirements
- Start with your preferred filling system; other systems can be added over time







## Peristaltic pump

As one of the most user-friendly filling systems available, our peristaltic technology combines precision and product safety.

### BENEFITS

- One-hand operation
- No format parts
- Perfect in combination with disposables



## Single-use filling

Do you need a fully interchangeable product path? The solution for your increased production requirements are our complete single-use filling systems:

- Single-use rolling diaphragm pump
- Single-use peristaltic pump tubing with stainless steel peristaltic pump
- Single-use filling needles



## Rolling diaphragm pump

Only the best of everything – Our rolling diaphragm pump combines the advantages of a defined filling volume with particularly careful product handling.

### BENEFITS

- Low shear, perfectly suitable for biopharmaceuticals
- Completely closed filling system
- Also available as a single-use variant



## Syntegon – Your reliable partner with expertise.

- ❑ More than 180 delivered FXS filling lines
- ❑ Over 15 years of experience in the processing of nested syringes
- ❑ All necessary filling and stoppering systems available including vacuum filling, vacuum stoppering, gassing,...



# Our Solutions.



## FXS Combi

An extremely flexible solution. Depending on the output and container, the machine with two, five or even ten positions processes pre-sterilized syringes, vials and cartridges at low, medium and high output rates. This implies a space-saving adaptation to production environment and line concepts.

## FXS 3100



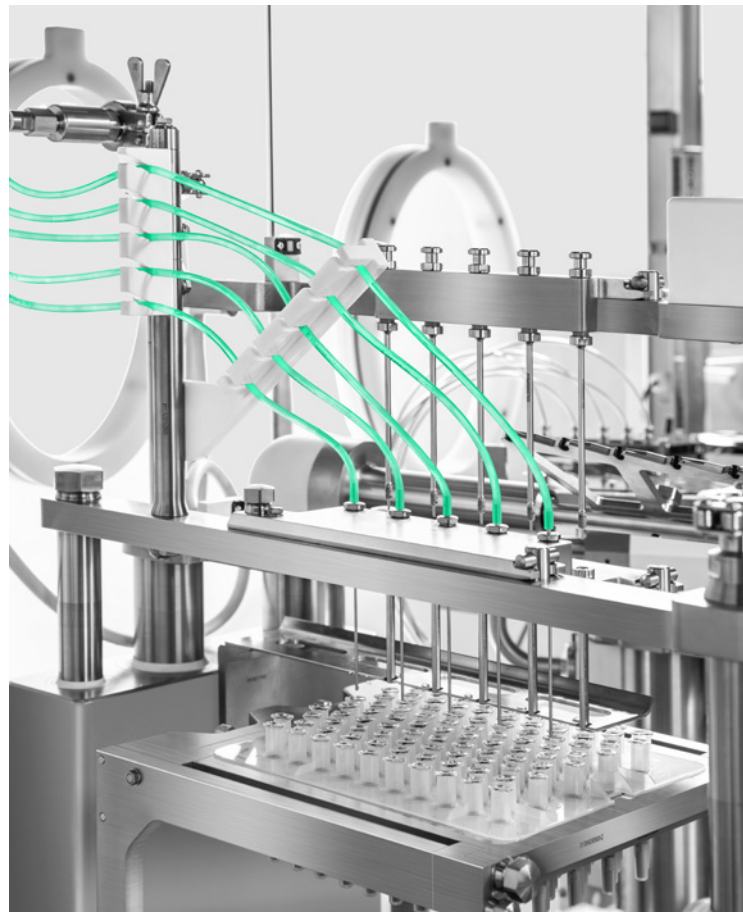
The ideal solution for the fully automatic filling and closing of pre-sterilized, nested syringes at medium and high production rates. One of the benefits is the easy size part changeover from tube/ rod to vacuum stoppering and from normal filling to vacuum filling.



## FXS 5100 series

Specifically designed for the processing of pre-sterilized, nested syringes at high and ultra-high speed. The syringe transport system sets new milestones in process quality and stability: The transport carriers are moved individually and independently from one another by servo-drives. The Pharma Handling Unit is used for the nozzle motion and provides extremely accurate filling, needle precision and adaptability to different formats and products.





## FXS 2052 Our Entry-level Model

The ideal solution for the fully automatic filling and closing of pre-sterilized, nested syringes at low and medium production rates. Available in emerging markets.

### BENEFITS

- Spacesaving and small footprint, optimal for inline layout
- Syntegon pharma surface quality: easy to clean and sanitize/sterilize
- Special nest feeding design, shorter nest exchange time and a higher output
- Gentle handling and less particle generation due to proved stopper inserting technology
- Easy size part changeover from tube/rod to vacuum stoppering

- Line integration with MBO/ABO and MTO/ATO
- Barrier systems (RABS, cRABS, Isolator)

### OPTIONS

- Peristaltic pump, stopper hopper, gas flushing, vacuum stoppering, fully automatic IPC
- Fully automatic In-Process-Control (IPC)
- Single use filling system possible

## Technical Data

FXS		2052
Filling volume	Vol. [ml]	0,5–20
Syringes	Ø [mm]	6,85–22,05

Technical data are subject to change



# FXS 3100 Our Automated Operator

The ideal solution for the fully automatic filling and closing of pre-sterilized, nested syringes at medium and high production rates – up to 355/min.

## BENEFITS

- ❑ Slim design: space-saving and easy to clean
- ❑ Operation from one side possible
- ❑ Upgrade to high-speed possible

## OPTIONS

- ❑ Syntegon peristaltic pumps
- ❑ Combi filling station
- ❑ Gassing during filling and closing
- ❑ Vacuum stopper insertion
- ❑ Vacuum filling
- ❑ Fully automatic IPC
- ❑ Reject station
- ❑ Barrier systems (RABS, cRABS, Isolator)

## Technical Data

FXS		3050	3100
Filling volume	Vol. [ml]	0,5–20 (50)*	
Syringes	Height [mm]	Up to 142 (162)*	
	Ø [mm]	6,85–22,05 (29,6)*	

\* Optional  
Technical data are subject to change





# FXS 5100 series Our High-speed Provider

Specifically designed for the processing of pre-sterilized, nested syringes at high and ultra-high speed – up to 600/min.

## BENEFITS

- Slim design: space-saving and easy to clean
- One side operation: optimal for inline and wall installation
- Precise and adaptable transport system
- Continuous filling and closing even during nest change
- Flexible and adaptable filling needle movement

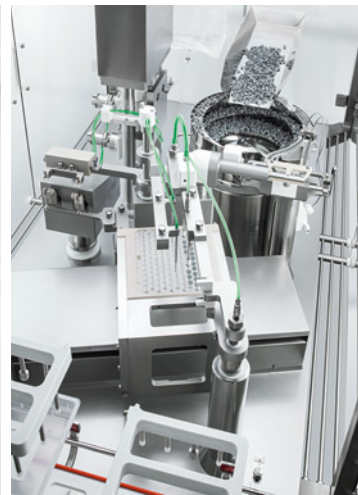
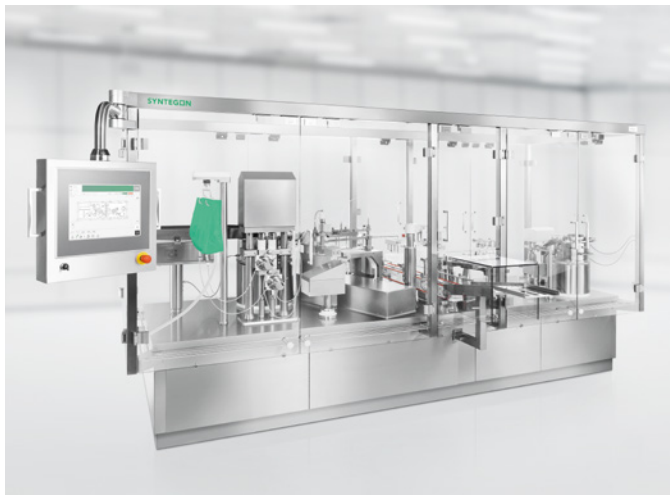
## OPTIONS

- Syntegon peristaltic pumps
- Combination filling station
- Gassing during filling and closing
- Vacuum stopper insertion and vacuum filling
- Fully automatic IPC
- Reject station
- Barrier system (RABS, cRABS, Isolator)

## Technical Data

FXS		5100	5101	5160
Filling volume	Vol. [ml]		0,5–20 (50)*	
Syringes	Height [mm]		Up to 142 (162)*	
	Ø [mm]		6,85–22,05 (29,6)*	

\* Optional  
Technical data are subject to change



# FXS Combi Our Adaptor

Filling and closing machine for nested syringes, vials and cartridges.

## BENEFITS

- All packaging types on one machine (nested syringes, vials and cartridges)
- Suited for all common Syntegon filling technologies
- Very precise filling operations for high product output
- Easy and quick format changes
- Integrated capping station for maximum pharmaceutical safety
- Flexible integration in complete line concepts

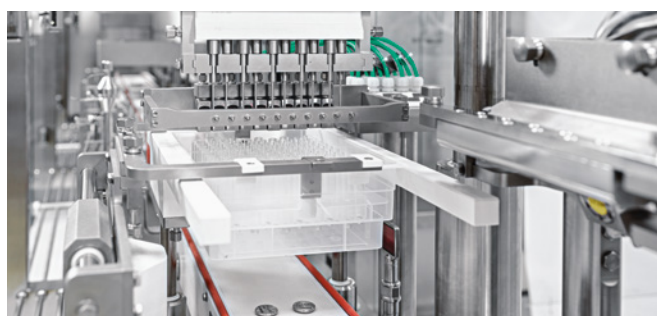
## OPTIONS

- Fully automatic IPC
- Vacuum filling and vacuum stopper insertion
- Upstream expansion with manual or fully automated tub and bag openers
- Flexible drug development with single-use filling systems
- Combination with RABS and Isolator
- Available as syringe, plastic syringe, cartridge, vial or combi application

## Technical Data

FXS		2021/2021C	2051/2051C	2101/2101C
Syringes	Vol. [ml]		0,5–20 (50)*	
	Height [mm]		Up to 142	
	Ø [mm]		6,85–22,05 (29,6)*	
Vials	Vol. [ml]		2R–20R (25R,30R)*	
	Height [mm]		35–60	
	Ø [mm]		16–30	
Cartridges	Vol. [ml]		3–10	
	Height [mm]		35–70	
	Ø [mm]		6,85–12	

\* Optional  
Technical data are subject to change



## FXS Combi – Glass Bead Insertion

Bead insertion station for nested carpules.

- For suspensions
- Glass and metal beads
- Optical monitoring of the insertion process
- Number of beads adjustable

# Highest quality in all process steps.

## Isolator Technology

All from one source –  
with over 40 years of experience.

- Integration instead of interfaces
- Aseptic and high-potent applications
- Rapid biodecontamination cycles
- Microbiological know-how
- Expertise in barrier systems



## De-nester for pre-filled syringes (USD)

Designed for denesting pre-filled syringes for in-line downstream processing. Nests are manually removed from the tub and placed on the infeed conveyor.

### OPTIONS

- Extended infeed conveyor for additional nests
- Automated removing of nests from tubs
- Automated stacking of nests and tubs
- Camera sensor to identify printing on tub





## Sterilizer

High-quality, safe and universally applicable machine for autoclaving, following the steam/air mixture process or the vacuum/steam process. Suitable for the sterilization of liquids in open or closed containers as well as of equipment.

SYNTEGON

### BENEFITS

- ❑ Innovative chamber design and robust construction
- ❑ High availability and process safety
- ❑ Flexible recipe editor
- ❑ Encapsulated door drive for clean room, maintenance and particle free
- ❑ Comprehensive documentation for faster validation and approval

## Inspection

Particles, cosmetic defects and leaks can reduce the quality of a product. Inspection technology reduces the risk of contamination, decomposition of active ingredients and discoloration.

### APPLICATIONS

- |                 |                          |
|-----------------|--------------------------|
| ❑ Needle shield | ❑ Product colour         |
| ❑ Fill height   | ❑ Stopper presence       |
| ❑ Body          | ❑ Stopper (side and top) |
| ❑ Particles     | ❑ Flange cracks          |



## Rod Insertion and Labeling (RIL)

A high-speed, integrated system for inserting plunger rods into syringes and applying labels – up to 400 syringes/min.

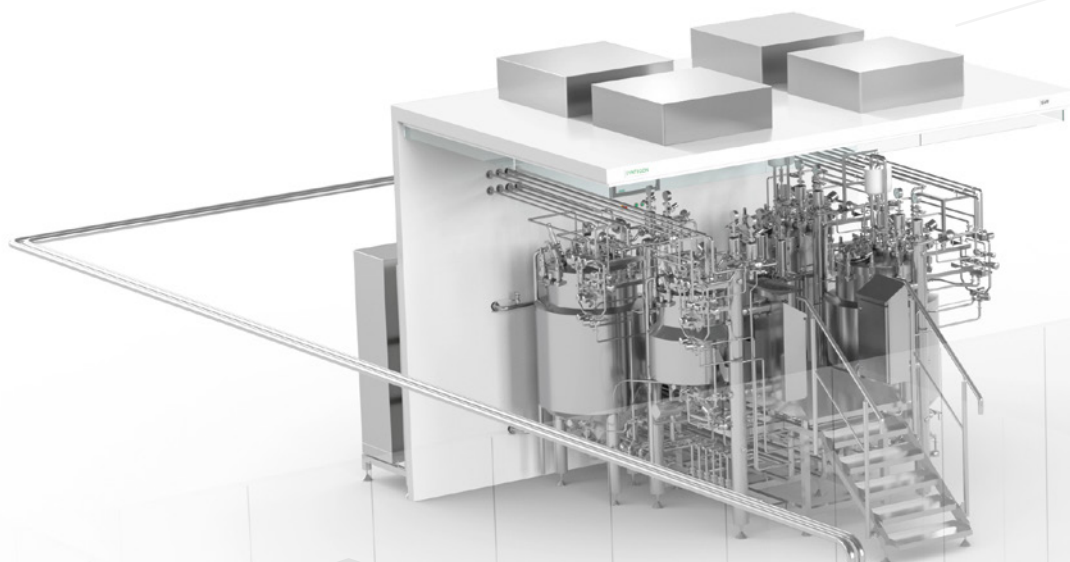
### BENEFITS

- ❑ Segmentation wheel allows intermittent motion for the rod insertion process
- ❑ High-speed product handling, rod insertion and labeling
- ❑ Independent controlled servo-driven mounting heads
- ❑ Total torque control ensures no movement of the rubber stopper

### OPTIONS

- ❑ Detection and rejection of faulty labels to avoid waste
- ❑ Sample tray for rejected syringes
- ❑ Dosing elevator (40-300 liter) for constant supply of rods and backstops

# Solutions for complete lines mean one hundred percent partnership.



**Formulation system  
(SVP)**

**Filling machine  
(FXS 3000/5000)**



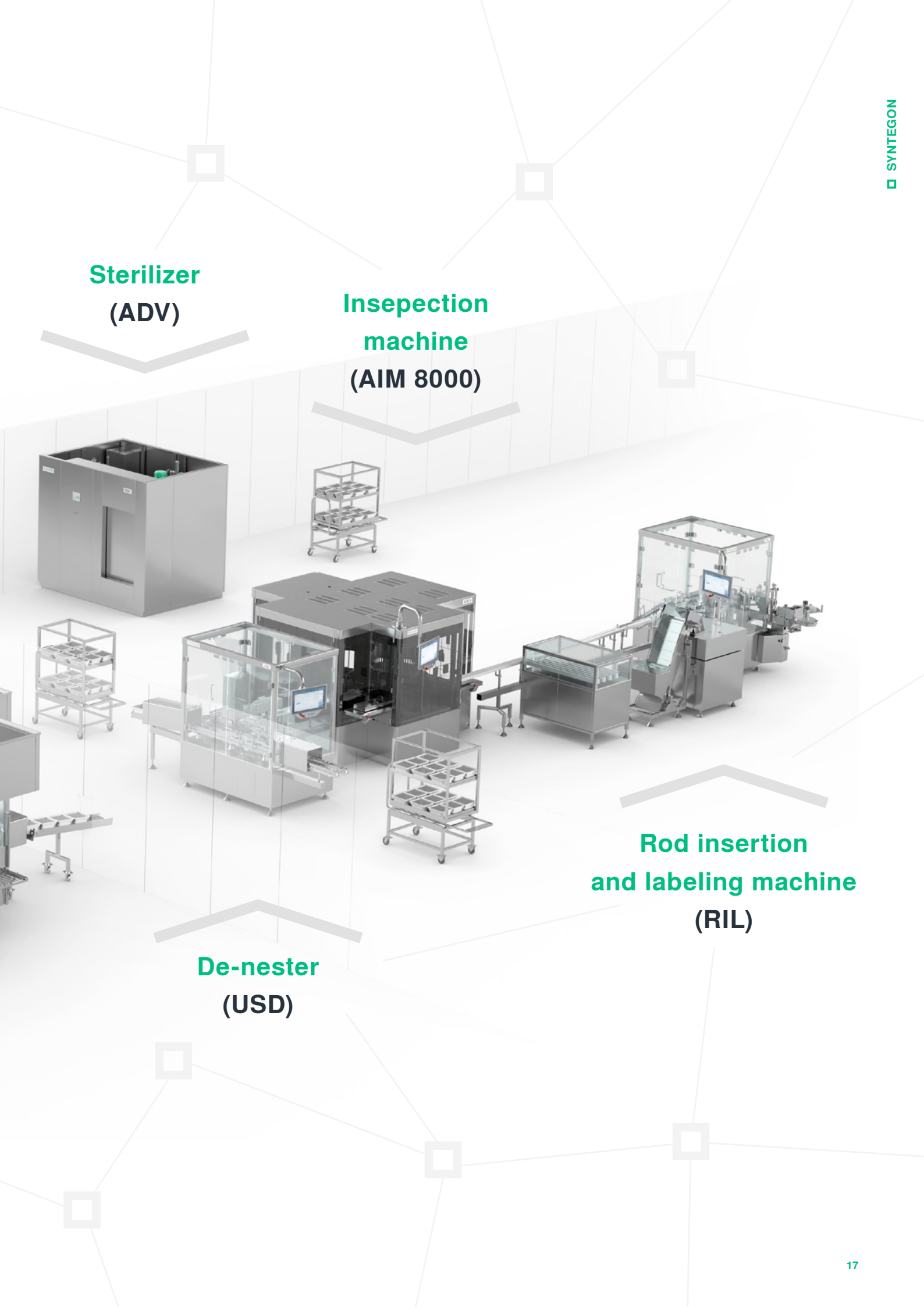
**Automatic  
tub opener  
(ATO 5000)**

**Sterilizer  
(ADV)**

**Insepection  
machine  
(AIM 8000)**

**Rod insertion  
and labeling machine  
(RIL)**

**De-nester  
(USD)**





# Digitization across the value chain.

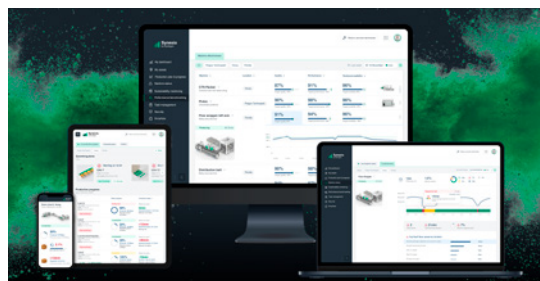


## Synexio

### Data transparency at all times

Synexio is a cloud-based software solution for the collection, evaluation and visualization of machine and production data. It will be offered in three different consecutive packages: "Monitor", "Uptime" and "Empower". Each of the packages contain features in different dimensions.

Syntegon's solutions are security-oriented and meet the highest data security standards. From outbound only collection, to encrypted transfer, to our ISO compliant processing, analysis and storage, your data security is our top priority



## BENEFITS

- Secure Connection
- Performance Transparency
- Partnership

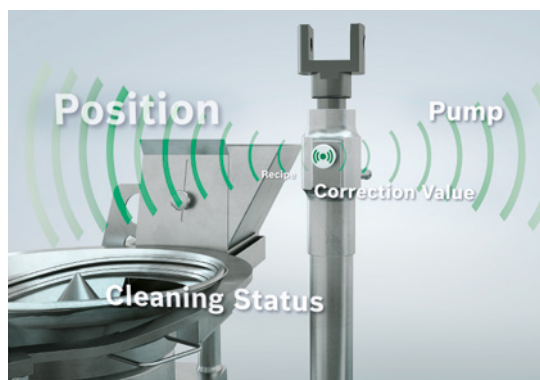
## Smart Pump

### Error detection and preventive maintenance

With Smart Pump, Syntegon is doing a transfer from the manual to the digital and connected world. RFID technology enables the storage and wireless transfer of important data from the piston pump to the filling machine.

## BENEFITS

- Reduction of human errors
- Comparison of the cleaning status and mounting position
- Visualization of filling statistics
- Integration of pump data in the batch report
- Link to documentation
- Preventive maintenance



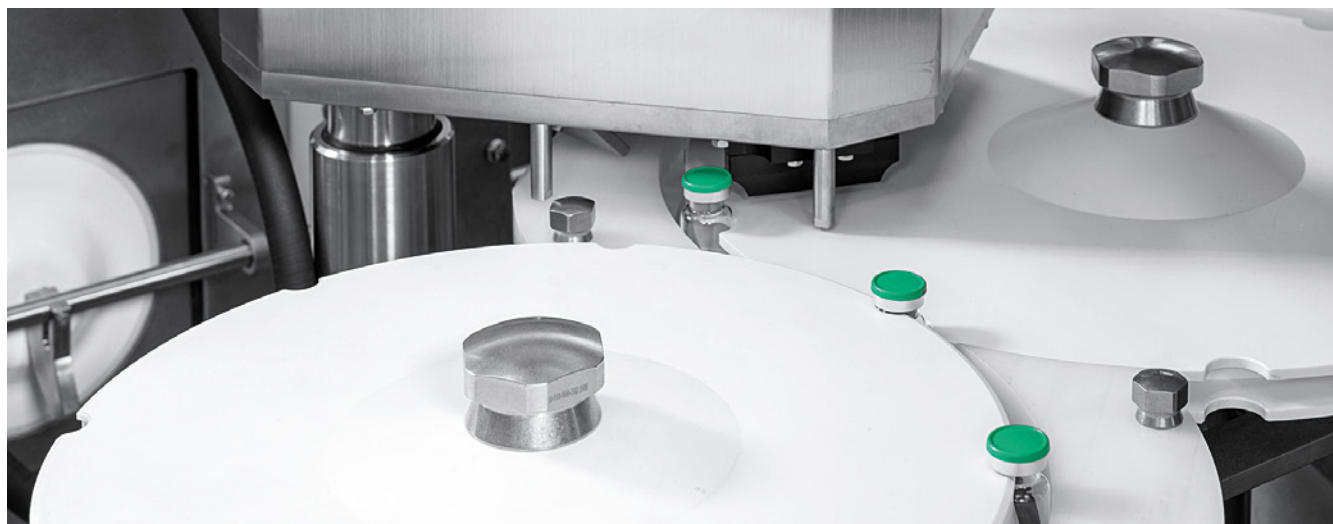
## Inline inspection systems

### The key to more quality

A guarantee for increased product safety and quality: integrated inspection systems, which, in addition to checking individual process steps, also offer the possibility of inspecting molded glass – even with the smallest container sizes.

## BENEFITS

- Reduction and prevention of product loss
- Immediate identification of defects and deviations in the production process
- Increase of production & product optimization



# Innovative services tailored to your needs.

A comprehensive service portfolio lays the foundation for smooth production processes. We at Syntegon support you throughout the entire machine life cycle, from spare parts management to digital line optimization. Service agreements are a key element of our portfolio structure. We minimize production risks and maximize the efficiency of your equipment by working with you as equal partners.

Together, we tailor our solutions to your individual needs. You benefit from fixed conditions and guaranteed services.

Our global network of experts supports you with maintenance planning, technical support, and modernizations, as well as operator training and expert services. With our digital solutions, you gain control over your production processes and create transparency on product and machine data – anytime, anywhere. Whether it is switching to sustainable materials or upgrading to automated technologies, together with us you will take the next steps towards the factory of the future.

How can we help you? Please get in touch with us:  
[www.syntegon.com/services](http://www.syntegon.com/services)



# Connect with our team.



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