

RTU Processing Solutions...

Pharma Liquid.



6.300

68.000

machines in the installed base

Count on it.

employees

39
locations

160
years of experience

1.5 billion
euros annual sales

patented inventions

1.200

service specialists

2.100

Syntegon Technology is your reliable partner for process and packaging technology in the global pharmaceutical and food industries. Whether you are an aspiring start-up or a global market leader, we offer intelligent and sustainable solutions for everyone.

Individual machines, systems or services – as a full-service provider, we take responsibility right up to fully integrated end-to-end solutions. Fields of application in the pharmaceutical industry are the production, processing, filling, inspection and packaging of liquid and solid active ingredients in all common

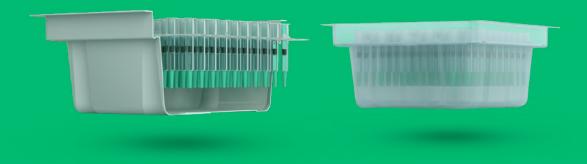
packaging materials. In the food industry, we offer solutions for the primary and secondary packaging of dry, liquid and frozen food as well as process technology for the production of confectionery.

We are at your side from project planning, development and implementation to comprehensive digitization, qualification and validation services. In addition, you always have access to our worldwide network of service specialists who support you throughout the entire machine life cycle.

Syntegon is a leader in automated solutions for ready-to-use (RTU) component processing, backed by a global service presence to support your operation wherever it might be. We have everything you need for fully harmonzied fill-finish processing, engineered for easy integration with your existing systems.

Seamless integration of automation equipment from a single trusted source allows you to more easily customize lines to your needs. This allows your to avoid the multi-supplier technology and equipment incompatibilities that can impact productivity, costs and safety.

Our tailored solutions ensure fully aseptic, fast, accurate, and cost-effective handling and filling with minimal waste. That means more reliable profitability for you and more secure access to medicines for everyone who needs them.





Syntegon's RTU Portfolio

- flexible solutions tailored to you

Whether you require solutions for small batch production or high-speed ready-to-use lines, we provide tailored solutions designed to optimize efficiency and meet the demands of your operation.



SMALL (UP TO 100/MIN)

There has been a noticeable shift in the pharmaceutical industry: more and more high-priced biotech drugs for limited patient populations, requiring flexible small batch filling solutions that achieve precise product yields at low output.

Small (up to 100/min)			
	Versynta FFP	The Versynta FFP (Flexible Filling Platform) is our modular and innovative platform for RTU containers with pre-developed and pre-tested modules. It delivers outputs of up to 3,600 containers per hour with 100% in-process control and full isolator integration.	
	Versynta microBatch	The gloveless Versynta microBatch working cell is the realization of robotic competence on the smallest scale. Following the trend towards even smaller batches, the highly flexible and fully automated setup allows the processing of aseptic and high-potent micro batches. Ensure the highest product quality and output with fast batch-to-batch changeovers, minimized product loss and a fully integrated machine and isolator.	



MEDIUM (100/MIN TO 300/MIN)

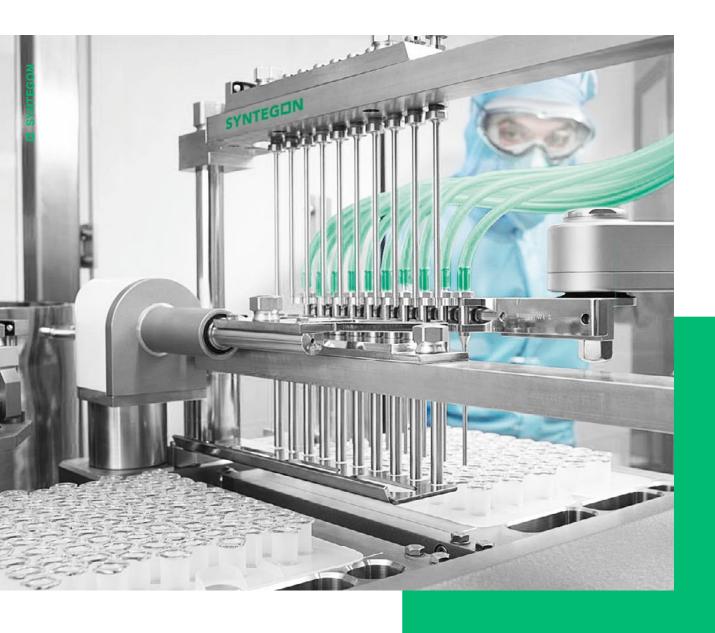
For moderate batch sizes, efficiently accurate filling and closing can take you from good to great.

Medium (100/min to 300/min)		
	FXS 2052	The FXS 2052 is an ideal solution for the fully automatic filling and closing of pre-sterilized, nested syringes at low and medium production rates. It can be flexibly integrated in room layouts and line concepts, and ensure safe and precise pharmaceutical processes.
	FXS 3100	The FXS 3100 is a great fit 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 Combi	An extremely flexible solution. Depending on the output and container, the FXS Combi with two, five or ten filling heads processes pre-sterilized syringes, vials and cartridges at low, medium and high output rates. This adaptable equipment saves space in the production environment and in line designs.

HIGH (MORE THAN 300/MIN)

Large scale production requires robust equipment that doesn't compromise on precision.

High (more than 300/min)			
	FXS 5100	Specifically designed for the processing of pre-sterilized, nested syringes at high and ultra-high outputs, the FXS 5100 knows speed. Our syringe transport system sets new standards in process quality and stability, while our robotic handling units are used for accurate filling and adaptability to different formats and products.	
	MLD Advanced	An upgrade to our wildly popular cartridge fill/finish platform, the MLD Advanced achieves 100% in-process control (IPC) at high speeds, confirming every syringe, vial or cartridge coming off the line is ready for the patient.	



Ready-To-Use expertise you can count on.

- Strong global install base—more than 180 delivered filling lines for RTU components
- 20 years of experience in the processing of nested syringes
- All necessary filling and stoppering systems available including vacuum filling, vacuum stoppering, gassing,...

Ready for everything RTU



The Syntegon RTU portfolio includes everything you need to deliver today's and tomorrow's pharma innovations — from filling equipment to isolator technology for automated aseptic processing of vials, syringes, and cartridges.

Annex 1-ready aseptic processing



Syntegon RTU fill-finish solutions operate seamlessly with each other to secure aseptic processing. Solutions are operator-friendly and easy to clean, meeting all GMP requirements and safety regulations, including the EU GMP Annex 1 revision.

Secure access to your medicines



Syntegon RTU filling technology enables consistent accuracy at any speed, protecting the integrity of innovative medicines. This ensures higher production efficiency, profitability and confidence in the supply chain.



The most advanced automation you'll ever need



Syntegon is a leading global developer of RTU fill-finish solutions. Our seamless product platform enables faster line changes and system reconfigurability, with readiness for easy upgrades to new capabilities as they become available.

Accelerate the ROI of your RTU



With its small footprint and optimized energy use, the Syntegon fill-finish platform can lower capital and operational costs significantly. Equipment is easy to operate and service, ensuring high uptime and consistent reproducibility.





Versynta FFP Our most flexible

An innovative, flexible filling platform that combines replaceable parts and modules for ultimate freedom of choice for container types and filling systems.

BENEFITS

- Complete solution for the entire filling process from a single source
- Compact filling and closing station
- Ready for all container types
- Changeover by parts size only, not modules, for faster and safer container and filling switches
- 100% in-process check weighing for all container types
- Possibility for vacuum-free high potent processing
- Fully integrated isolator for aseptic and aseptic potent production

- Short cycle time for biodecontamination
- Precise and sensitive handling
- Easy freeze dryer integration

OPTIONS

- Output: up to 3,600 containers/h
- Application areas: RTU processing
- Robotic systems: Pharma Handling Unit
- Isolator with integrated air management

Technical Data

Versynta FFP		
	Vol. [ml]	0,5–10
Syringes	Height [mm]	35–110
	Ø [mm]	8,65-17,05
	Vol. [ml]	2R-30R
Vials	Height [mm]	35–75
	Ø [mm]	16–30
Cartridges	Vol. [ml]	1–3
	Height [mm]	35–95
	Ø [mm]	8,65-11,6

Technical data are subject to change







Versynta microBatch Our precision performer

The gloveless Versynta microBatch is our smallest-scale fully automated robotic solution for the processing of aseptic and high-potent micro batches.

BENEFITS

- ☐ Gloveless isolator for shortest biodecontamination
- Fully automated robotic solution
- Fully integrated machine and isolator unit
- Engineered for fast batch-to-batch changeovers and to minimize product loss
- Work cell approach for integrated air management
 no interface towards building
- High flexibility, suitable for all RTU syringes, cartridges and vials (classical stoppers and caps as well as press-on caps)
- Maximum security filling with 100% in-process control
- Fast installation and validation
- Prepared for aseptic and potent production
- Ideal for the small production outputs of clinical trials, cell and gene therapy and start-ups

OPTIONS

- □ Up to 500 containers/h
- Nest operation (syringes, cartridges, vials): 500/h
- One-by-one filling (vials): up to 120/h
- RTU processing
- □ Vials: 2R-50R
- Nested syringes: 0.5–20 ml
- Robotic systems and isolator
- Machine dimensions: approx. 3 x 2 x 3m
- Isolator cell: approx. 1.6 x 1.5m

Versynta microBatch		
Filling volume	Vol. [ml]	0,5–20
Syringes	Ø [mm]	6,85-22,05

^{*} Optional Technical data are subject to change



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

- □ Space saving 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 handing and less particle generation due to proven 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 in-process control (IPC)
- Single use filling system possible

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

^{*} Optional 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
- Combination filling station
- Gassing during filling and closing
- Vacuum stopper insertion and vacuum filling
- Fully automatic IPC
- Reject station
- Barrier system (RABS, cRABS, Isolator)

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

^{*} Optional Technical data are subject to change





FXS Combi Our adaptor

An extremely flexible filling and closing machine for processing nested pre-sterilized syringes, vials and cartridges at low, medium and high output rates.

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 applications

Technical Data

FXS		2021/2021C	2051/2051C	2101/2101C
	Vol. [ml]		0,5-20 (50)*	
Syringes	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	
	Vol. [ml]		3–10	
Cartridges	Height [mm]		35-70	
	Ø [mm]		6,85-12	

Technical data are subject to change

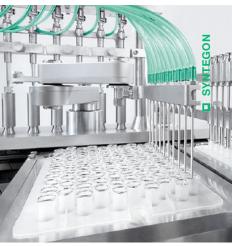


FXS Combi – Glass Bead Insertion

Bead insertion station for nested carpules.

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







FXS 5100 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)

FXS		5050	5100
Filling volume	Vol. [ml]	0,5-20) (50)*
Syringes	Height [mm]	Up to 142 (162)*	
	Ø [mm]	6,85-22,0	6,85-22,05 (29,6)*

^{*} Optional Technical data are subject to change







MLD Advanced our accelerator

Designed with 100% in-process control and dedicated inspection solutions for maximum protection of high-vaue RTU syringes, vials and cartridges at high speeds.

BENEFITS

- Combines proven technology for tub/nest handling with high-speed filling, up to 400/min
- Fully automatic 100% in-process control (IPC)
- Suitable for all RTU containers (syringes, cartridges, vials)
- Modular linear conveyor allows easy addition of process stations (e.g. gassing or beading stations)
- Annex 1 compliant

OPTIONS

- Glass and polymer syringe handling possible
- Maximized product yield with MaxPro features
- Vent tube and vacuum stoppering available
- Multiple filling options available, including vacuum filling
- □ Flexible machine layouts (L-shape, U-shape, ...)

Technical Data

MLD Advanced		
	Vol. [ml]	0,5–10
Syringes	Height [mm]	35–110
	Ø [mm]	8,65-17,05
Vials	Vol. [ml]	2R-30R
	Height [mm]	35–75
	Ø [mm]	16–30
Cartridges	Vol. [ml]	1–3
	Height [mm]	35–95
	Ø [mm]	8,65-11,6

Technical data are subject to change

Your partner in responsible medicine production.

With intelligent solutions for safe and highquality production, processing, filling, inspection, and packaging of medicines, Syntegon has been helping global pharmaceutical customers improve people's lives for more than 160 years.

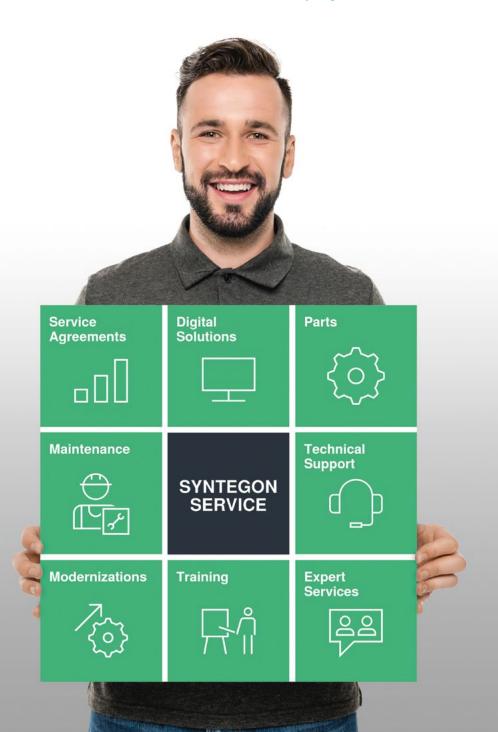
Syntegon actively works to make a positive impact on society and the environment. This includes the development of sustainable packaging solutions, reducing energy consumption and pursuing ambitious goals to lower emissions. Find out more at Syntegon.com/responsibility

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



LEVEL

LEVEL

Service Agreements.

We have packaged our Service offerings into Service Agreements for your convenience.

LEVEL LEVEL LEVEL Packed with: LEVEL Packed with: □ On-site Manager Packed with: ■ Expert Services ■ Expert Services Packed with: □ Repairs ■ Repairs ■ Repairs □ Training □ Training Packed with: ■ Training Packed with:

Maintenance
Inspection ■ All Parts ■ All Parts ■ All Parts □ Maintenance ■ Maintenance ■ Maintenance □ Inspection □ Inspection □ Inspection Remote Technical Support ■ Remote Technical Support ■ Remote Technical Support ■ Remote Technical ■ Remote Technical □ Remote Technical Support Support Support □ Contract Fulfilment Manager Contract Fulfilment Manager Contract Fulfilment Manager □ Contract Fulfilment □ Contract Fulfilment Manager Manager + Add-on Services + Add-on Services + Add-on Services + Add-on Services + Add-on Services

Effective asset and maintenance management both increases the lifespan and improves the performance and reliability of your equipment. This means fewer breakdowns, fewer subsequent repairs and less unplanned equipment downtime. With our extensive equipment expertise, let us be your partner to develop and deploy the optimal maintenance strategy for your production needs.

We support you with standardized packages from inspection to guaranteed equipment performance of your machines. All levels are available at a fixed price and can be customized with additional services.

Your benefits



LEVEL

Minimize risk

Together we minimize production risk.



Predictable

Plan ahead and predict your costs.



Simple

Simplifying complex processes.



Want to know more about our services?
Scan the QR code.

Ready for everything RTU.





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