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All about Pre-filled Syringe Systems Training Course

Klaus Ullherr
Senior Product Manager
Syntegon Technology

April 21st – 22nd, 2023 Venice





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Fill and Finish - Introduction -



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Important norms: ISO 11040-4/-7

	DEUTSCHE NORM	juli 2017	
	DIN ISO 11040-4	DIN	INTERNATIONAL STANDARD ISO 11040-7
ICS 11.040.25	Ersatz für DIN ISO 11040-4:2007-10		First edition 2015-04-01
<p>Vorgefüllte Spritzen – Teil 4: Spritzenzylinder aus Glas für Injektionspräparate und sterilisierte und vormontierte Spritzen zur Abfüllung (ISO 11040-4:2015)</p> <p>Prefilled syringes – Part 4: Glass barrels for injectables and sterilized subassembled syringes ready for filling (ISO 11040-4:2015)</p> <p>Seringues préremplies – Partie 4: Cylindres en verre pour produits injectables et seringues pré-assemblées stérilisées préremplissables (ISO 11040-4:2015)</p>			<p>Prefilled syringes – Part 7: Packaging systems for sterilized subassembled syringes ready for filling</p> <p><i>Seringues préremplies – Partie 7: Systèmes d'emballage pour les seringues stérilisées prêtes à l'emploi préremplissables</i></p>

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PDA Technical Report

Technical Report No. 73

Prefilled Syringe User Requirements for
Biotechnology Applications

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Bulk Processing – some remarks

Challenges:

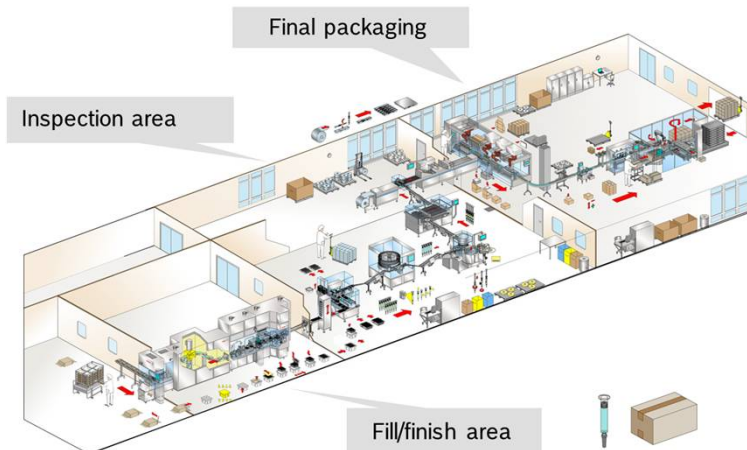
- Syringes not stable for transport
- Siliconization has to be adapted to each format
- Not flexible for new components (tip cap, LLA)
- Syringes with needle cannot be processed in the tunnel
- Can be done with autoclaves → high effort, batchwise process




Advantages:

- Proven sterilization process
- Proven transfer to the filling area
- Cheaper packaging material
- Full control of the manufacturing / siliconization process













Nested syringe processing




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Tub introduction into a RABS/Cleanroom


E/D	C	C	A		
					
					





















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Tub introduction into an Isolator

E/D	D/C		A		
					
					
					



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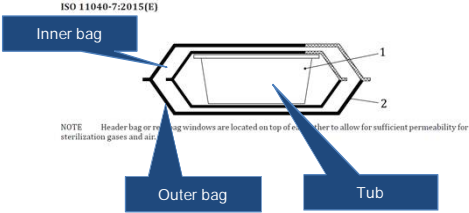
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Trend for (high speed) fill/finish lines

(Fully automatic) No touch-transfer (NTT) with double bags in order to avoid e-beam

ISO 11040-7:2015(E)



NOTE Header bag or bag windows are located on top of the tub to allow for sufficient permeability for sterilization gases and air.

Picture ISO 11040-7

WID - Automatic Bag Closer

Bag specification


SYNTEGON
PROCESSING & PACKAGING

Change log for the document			
Date	Initial	Version	Comments
10/16/2021	SEMF/CA	1	Creation of the draft version
10/22/2021	SEMF/CA	2	Inserting new images (chapter 2) and sources (chapter 1)

Scope:
The scope of this document is to provide an overview of the criteria that the packaging should have in order to be processed by the filling line.


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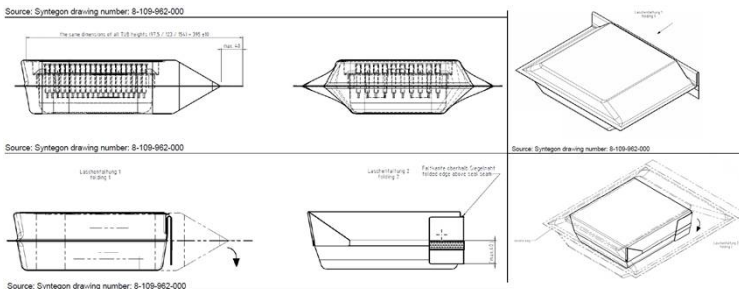
Trend for (high speed) fill/finish lines


Folding of the inner bag is crucial

Size of the bag

Folding of the bag

Material of the bag





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Fill and Finish

Automatic Bag Opening



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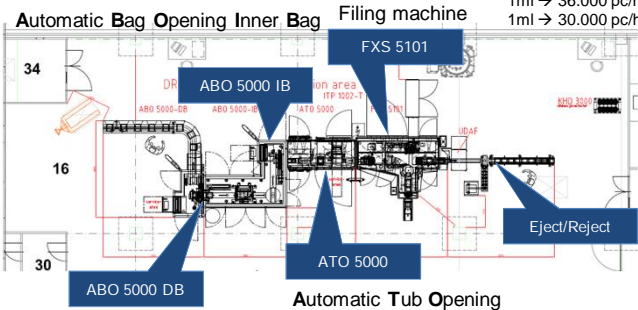
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Line Layout – high speed line

Capacity:
 1ml → 36.000 pc/h (w/o IPC)
 1ml → 30.000 pc/h (1% IPC)



Automatic Bag Opening Inner Bag

Filing machine

Automatic Bag Opening Double Bag = outer bag

Automatic Tub Opening

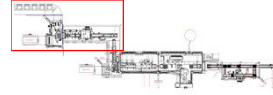
Eject/Reject

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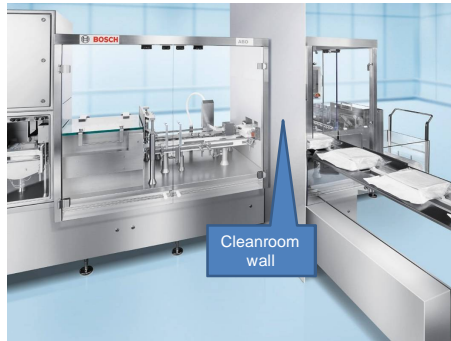
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Double bag opening

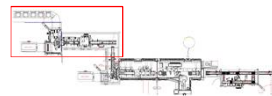


View from ABO Double Bag

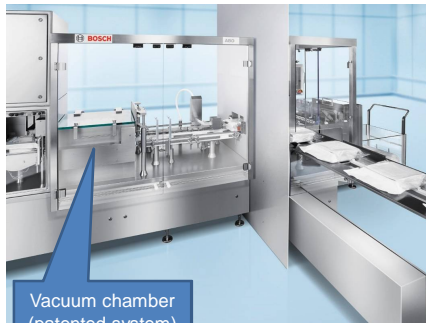


Cleanroom wall

Double bag opening



Arrangement / preparation for cutting the inner bag (patented system)



Vacuum chamber (patented system)



PDA 15

Filling line in RABS with Automatic Bag and Tub Opening

ABO LF-hood

ATO LF-hood

FXS LF-hood

ABO 5000

ATO 5000

FXS 3100

Stopper supply for double bags (pre-sterilized)

Clear separation of the cleanroom areas (two base frames)

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Filling line under isolator with Automatic Bag and Tub Opening

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Automatic Bag Opening in detail

Requirements

- Up to 6 tubs/bags per minute
- Clear separation of clean room areas
- Protection of the tub (by the bag) as long as possible
- Safe separation of tub and bag
- No contact bag outside – tub outside
- Minimizing the risk of particles
- Only one piece of waste



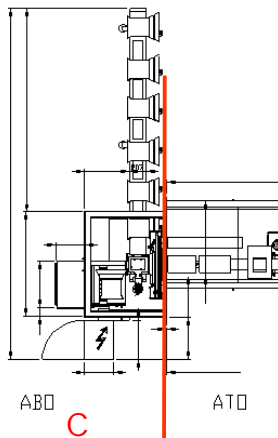
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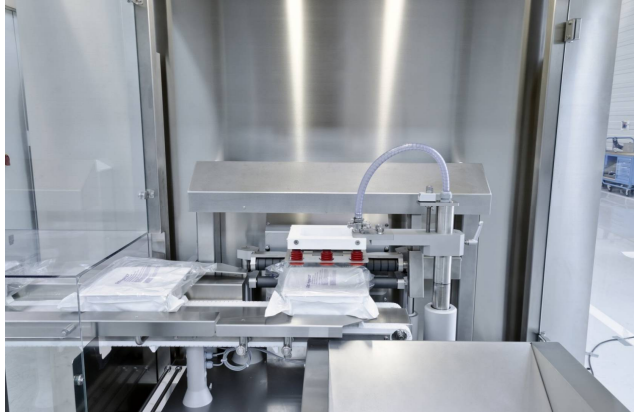
Automatic Bag Opening



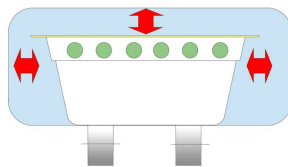
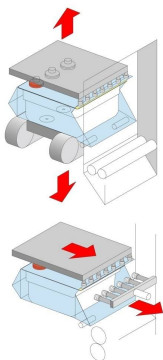
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Automatic Bag Opening – Basic Configuration



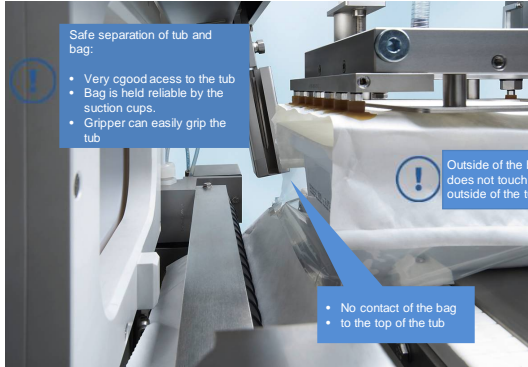
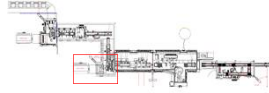
Aseptic Tub Transfer – a Bundle of Measures



No contact bag outside – tub outside, especially at the top of the tub.

Protection of the tub (by the bag) as long as possible. Removal just before the transfer.

Automatic Bag Opening



Safe separation of tub and bag:

- Very good access to the tub
- Bag is held reliably by the suction cups.
- Gripper can easily grip the tub

Outside of the bag does not touch the outside of the tub

- No contact of the bag to the top of the tub

Line video



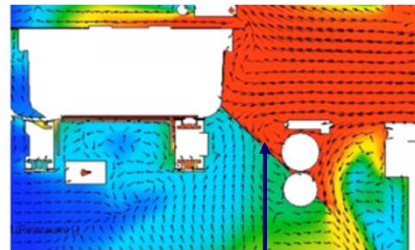
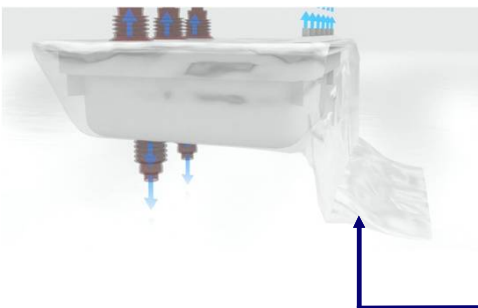
NTT video



NTT animation



Automatic Bag Opening – CFD Simulation




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Automatic Tub Opening



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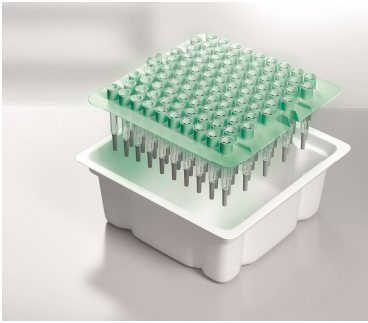
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Tub Opening

Requirements

- Up to 6 tubs/min
- Minimum particle generation
- Reliable gripping of the cover sheet
- Absolute reliable functionality



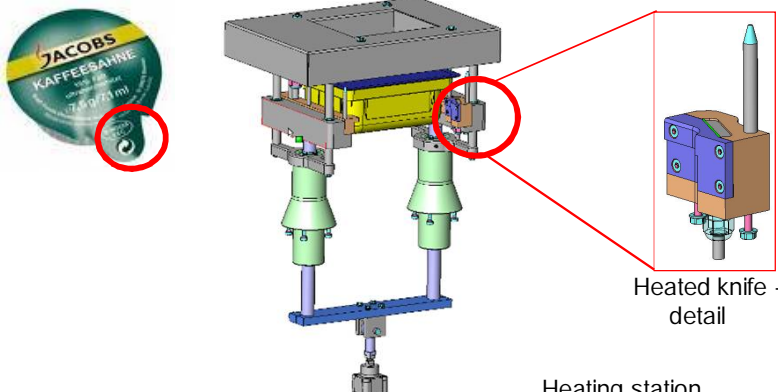
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PDA 25

Coffee Cream Concept – pre-Determined Breaking Line



Heated knife - detail

Heating station

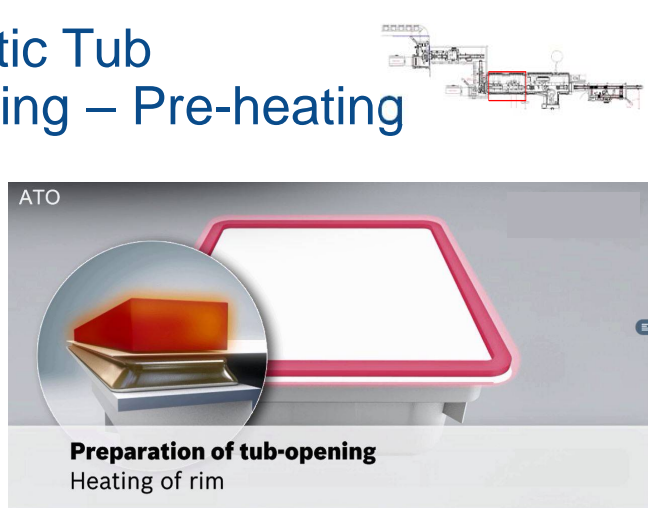
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Automatic Tub Opening – Pre-heating



Pre-heating of the tub rim. Temperatures adjustable at HMI for different qualities of packaging material (range from approx. 80°C to 120°C , typically around 100°C →

- Less particles
- Facilitates the opening process

ATO

Preparation of tub-opening
Heating of rim

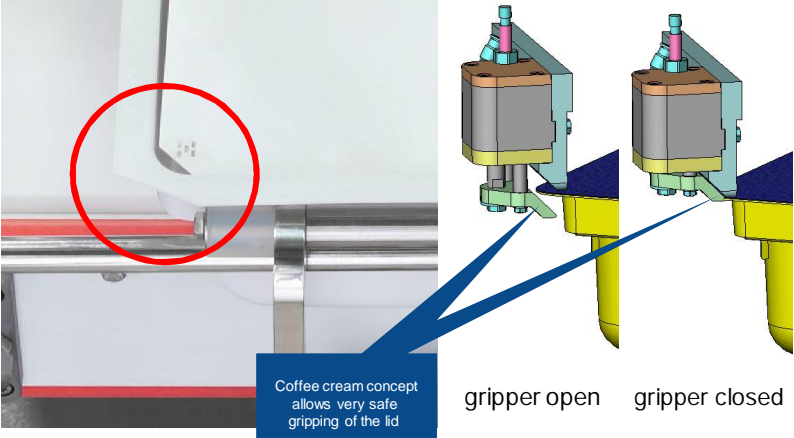
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Tub Opening – Detail



Coffee cream concept allows very safe gripping of the lid

gripper open gripper closed


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Automatic Tub Opening



Camera for checking proper lid removal

Heating frame for heating up the tub rim

Wall installation (option)

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Fill and Finish

Filling



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Fill/finish - Requirements

Syringe specific requirements:

- Up to 600 syringes / min ¹⁾
- Precise transport system
- No contact of the insertion tube with the syringe
- Suitable for all available filling systems
- Stoppering immediately after filling
- Transport of the tub



¹⁾ 16head up to 57.600/h

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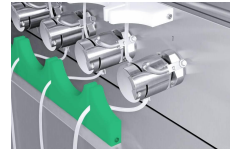
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Overview of Filling Systems

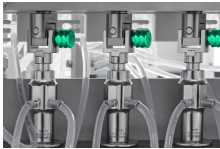
- Rotary valve piston pumps
- Peristaltic pumps
- Time pressure filling system
- Mass flow filling system
- Rolling diaphragm pumps
- Combi filling station



Rolling Diaphragm Pumps



Peristaltic Pumps



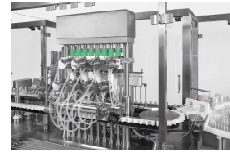
Piston Pumps



Time Pressure



Mass Flow



Combi Filling Station

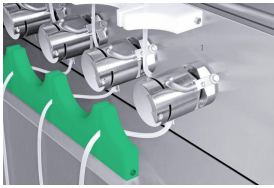
Filling System Comparison

		PRODUCT PROPERTIES							
		Similar to water	High viscosity	Protein/ Biotech	Sus-pension	Warm/ Cold filling	Crystallizing / Sugar containing	Minimum product loss	Repro-ducibility / Speed
FILLING SYSTEM	Piston Pump	++	++	0	0	0	0	0	++
	Peristaltic Pump	++	0	++	+	0	+	+	+
	Time Pressure	++	-	+(+)	++	0	++	++	+
	Mass Flow Metering	++	0	+	0	++	+	0	+
	Rolling Diaphragm Pump	++	0	+	0	0	+	0	+

- not possible / not reasonable
 0 possible with restrictions
 + possible solution
 ++ preferred solution

Peristaltic Pumps Filling System

- Pump tubing (two parallel hoses) is compressed for product flow
- Pump tubing is a closed system from product supply up to the filling needle
- Accuracy is maintained between range of 0.5% to 1.5% of nominal fill volume, depending on tubing size and speed
- Two sizes available (up to 30ml, up to 500ml)
- Preferred solutions for single use applications



Peristaltic Pumps Filling System

Benefits

- First choice for shear sensitive products (protein)
- First choice for single-use-filling systems
- Easy handling (one hand operation)
- Tubing is the only size part
- Closed system

Points to consider

- Viscous products



Peristaltic Pump with single-use filling system in a combi filling station



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Peristaltic Pump on syringe filler



Individual stopper presence check with sensors to check rod position



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Rotary Valve Piston Pump Filling System

- Pumps available in either Stainless Steel or Ceramic
- Ceramic pumps fit in same pump stations as Stainless Steel



- Made of Al₂O₃ (99.7%) or ZrO₂
- High wear resistance
- Chemical resistance in acid and alkaline range



- Made of 316 L stainless steel
- Parts are manufactured from one piece, no welded seams
- Electropolished



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Rotary Valve Piston Pump Filling System

Benefits

- Accurate, repeatable fill volumes, also at high speed
- Most popular pump type, very well known
- No seals
- Simple assembly
- Easy to clean and sterilize

Points to consider

- Crystallising products
- Longer CIP/SIP cycle time than TPF (more steel)
- Not applicable for high temperature filling >35°C



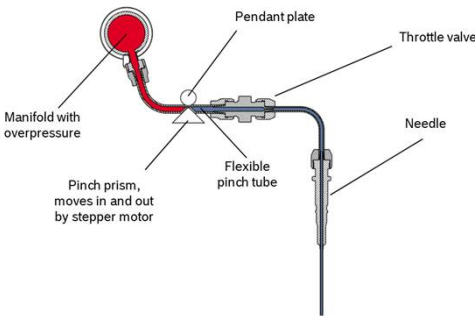
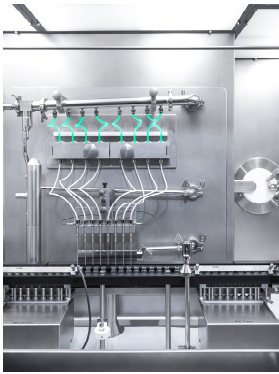
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Time Pressure Filling System

Product path from manifold to container

Manifold with overpressure

Pinch prism, moves in and out by stepper motor

Pendant plate

Flexible pinch tube

Throttle valve

Needle

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Time Pressure Filling System

Benefits	Points to consider
<ul style="list-style-type: none"> Easy size changeover Very simple mechanical set-up Easy cleaning Closed system No problems with crystallising products CIP/SIP handling, faster cycle 	<ul style="list-style-type: none"> Accuracy if product viscosity is highly dependent on temperature Oily products Control system needs educated staff

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Combi Filling Station



Rotary valve piston pump



Peristaltic pump



Rolling diaphragm pump



Time-pressure-filling

In Process Checkweigh under Isolator – Detail



Weighing cells



Gripper for syringes

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Filling Laboratory – Content of typical test protocol

- Customer name
- Product name
- Filling Volume
- Filling size parts (needle, tubing, ...)
- Output
- Design of filling system and product header
- Parameters of filling system (e.g. speed of peristaltic pump, acceleration)
- Parameters of filling needle movement

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Fill and Finish

Stopper Insertion Principles



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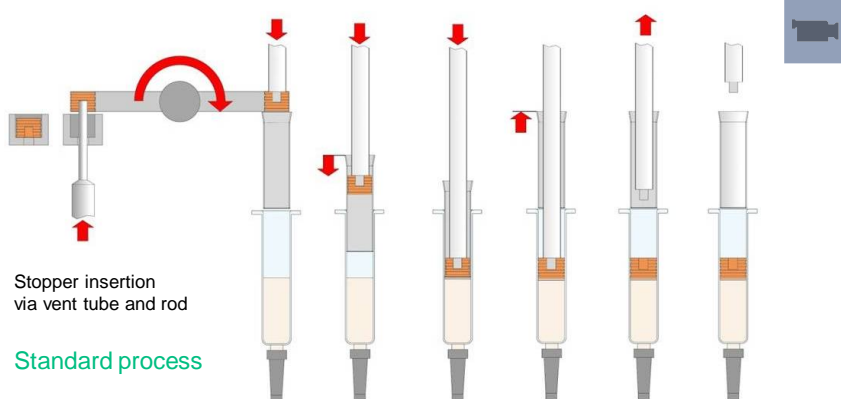
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Reasons for different stopper setting methods

- Coated stoppers, sensitive to compression
- Residual oxygen when filling oxygen sensitive products
- Residual air bubble when using autoinjectors or pen systems
- Viscous filling products
- Sensitive polymer syringes



Stopper insertion principles



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Stopper insertion principles

Stopper insertion via vent tube and rod + gassing

For reducing residual oxygen

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Slides for hands on Training

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Stopper insertion principles

Stopper insertion by vacuum

For coated stoppers and/or to reduce air bubble

Combi vacuum+ vent tube

For very low stopper positions in the syringe

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Stopper insertion principles

To minimize air bubble and the residual oxygen

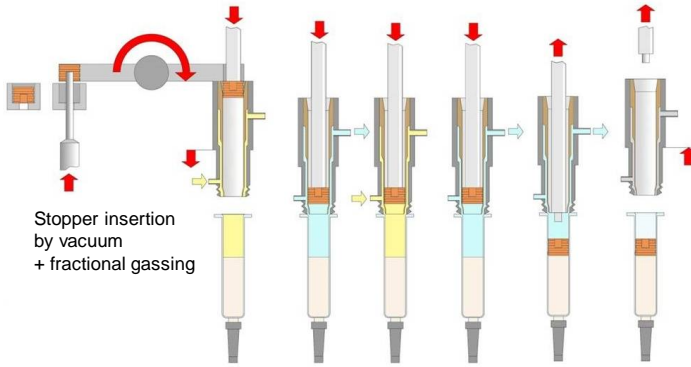
Stopper insertion by vacuum + gassing

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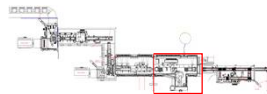
Stopper insertion principles



Stopper insertion by vacuum + fractional gassing

For lowest residual oxygen values

Stoppering station



PDA 53

Basic Configuration Stopper Supply



Detection of stopper presence perrow (not individual):
When one or more stopper(s) is (are) not present in vent tube
→ rod is not lifted
→ sensor is blocked

Stopper re-supply, made of stainless steel

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New Annex 1 - Stopper Supply via port operation from the outside

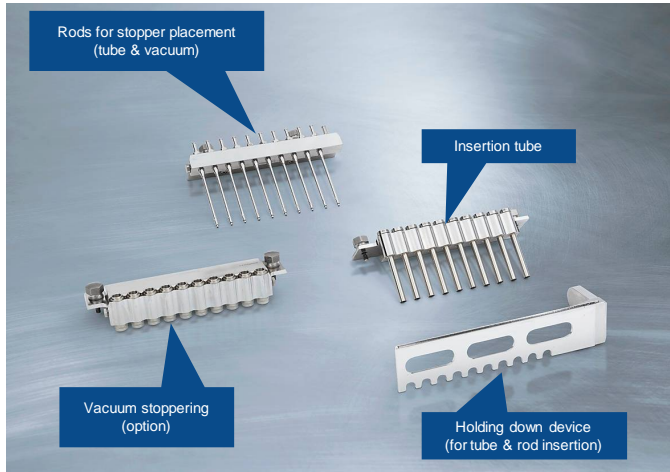


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Size Parts Stopper Placement



Fill and Finish




Special topic: Vacuum filling

PDA 57

Vacuum filling / stoppering

Animation Video



Pump station, reinforced for vacuum filling

Rods for stoppering

Filling needles


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Vacuum filling / stoppering



Transport carriers

Teflon hoses for filling hyaluron acid


Suction cups (silicone) for sealing the syringes, combined for filling and stoppering

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Vacuum filling / stoppering



Level control intermediate tank by gravity
→ more safety, more reliable


Vacuum for product supply from onsite tank
Vacuum for degassing of product
Pressure for product supply towards filling pumps / filling station

Special Intermediate tank for product supply for minimizing air bubbles

Filter units for:
▶ vacuum filling
▶ vacuum stoppering
▶ intermediate tank

All outlets at the bottom for minimizing air bubbles

Product supply from below for minimizing air bubbles



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Manufacturing Aspects

Regarding Filling, Finishing and Assembly

RABS/Isolator/Stopper Supply/End of filling line



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RABS Stopper Supply Including Sliding Pane



Stopper loading from operation side

Easy logistics / no crossing of the line



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Nested Syringe Filling Machine with Isolator



Stopper supply with exchangeable Port

Wash down air ducts



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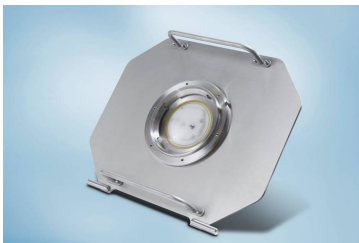
Isolator Stopper Supply



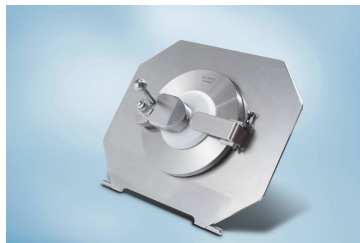
Exchangable port for stopper supply

Exchangeable Port for Stopper Supply

Port Getinge



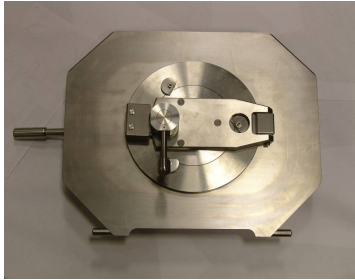
Outside view



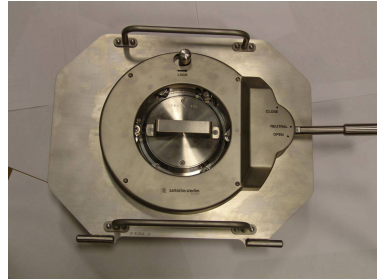
Inside view

Exchangeable Port for Stopper Supply

Port from Sartorius stedim for BD TSCF stoppers (former IDC)



Outside view



Inside view

Topics for Mock-Up (Selection)

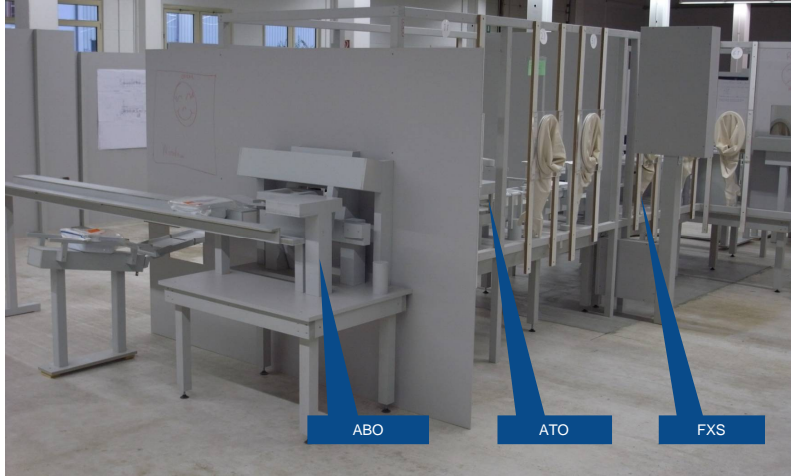


- Positioning and number of gloves
- Media connections
- Stopper supply
- Position of particle and microbiological monitoring
- Handling inside the barrier system: Start up of line, line clearance and trouble shooting

Conclusion: After the mock-up major adaptations of the machine design can be necessary for optimized barrier system use.



Mock Up for Isolator & RABS



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Mock Up for Isolator & RABS



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Tub Reject

Nest Matrix showing good/bad syringes

Seperate discharge conveyor with pneumatically operated turn switch

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PDA 70

Manufacturing Aspects

Regarding Filling, Finishing and Assembly

Combi Filling – Robotic Filling

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New Trends – Packaging Material – Pre-Sterilized (Selection)

Tub & nest approach (syringes, vials and cartridges)



Packaging material pictures by Gerresheimer



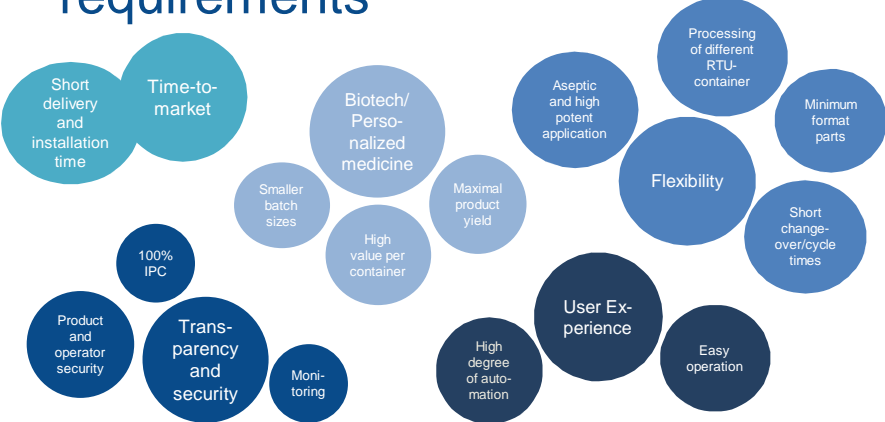
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Market trends and requirements



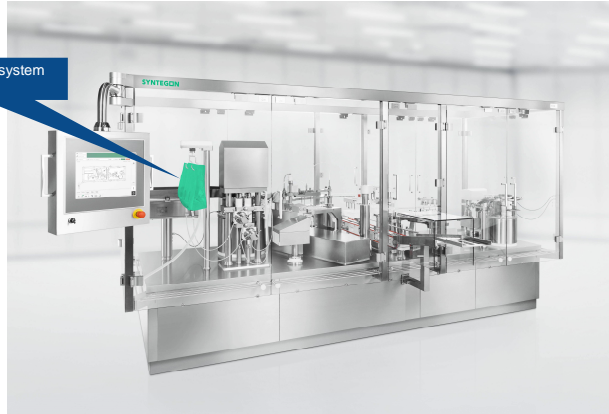


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Combi nest filler for syringes, vials, cartridges

Single use filling system PreVAS

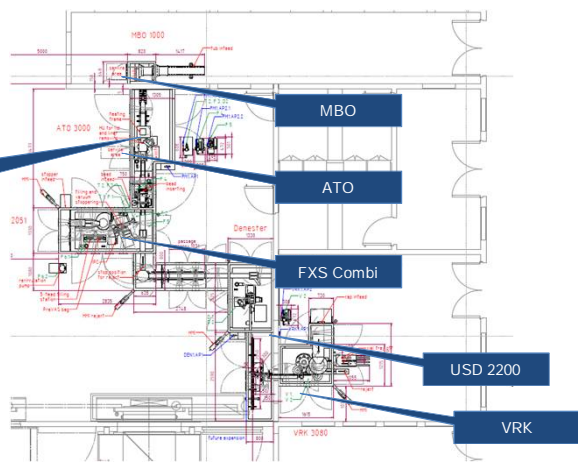


Combi Nest filler line

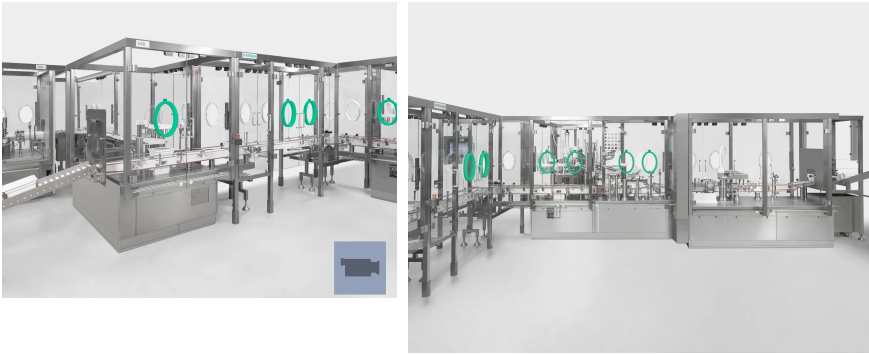
Glass bead insertion for "old" insulins (suspension)



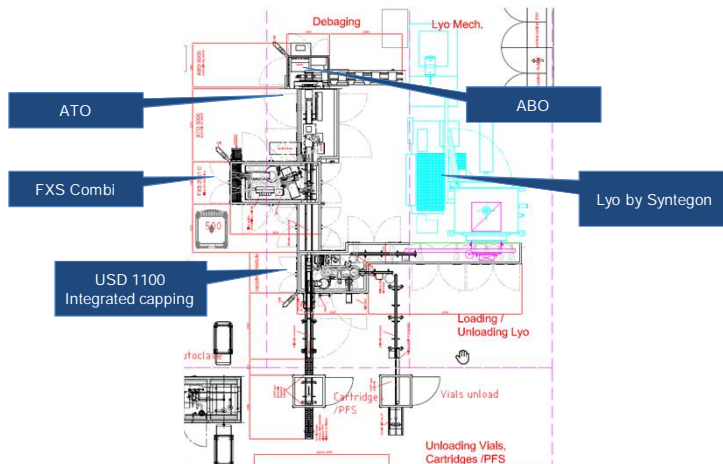
Unique at Syntegon: Glass bead insertion for nested cartridges



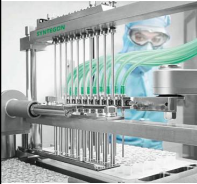
Combi nest filler for syringes, vials, cartridges



Combi Nestfiller line



Longterm vision



*"The design of equipment used in aseptic processing should **limit** the number and complexity of aseptic **interventions by personnel**. (...) Automation of other process steps, including the use of technologies such as **robotics**, can further **reduce risk to the product**."*

FDA Guidance for Industry Sterile Drug Products, produced by aseptic processing cGMP, Sept. 2004



Flexible Filler customized





Machine and Isolator = one unit

Versynta FFP – Flexible Filling Platform



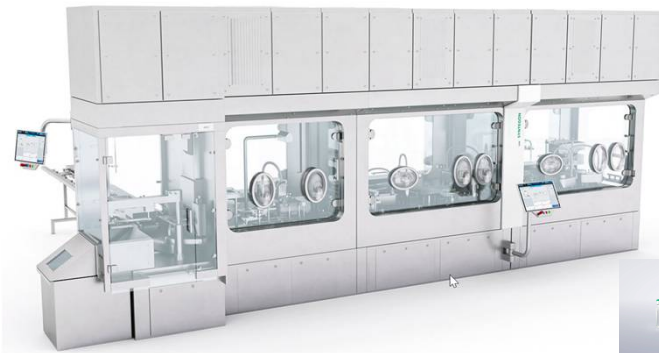
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Machine and Isolator = one unit

Versynta FFP – Flexible Filling Platform



Animation



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FFP - Detail filling station



Video syringe



Video vial



Dose in 00:00 - 38

Gloveless isolator

Versynta microBatch



Development project Versynta - microBatch: Robotic competence on the smallest scale

- Creating a new industry standard for fill/finish of small batches by using a development partnership
- Clear trend to smaller batches for different types of ready-to-use containers and high value drugs
- Highly flexible and automated production cell
- **Gloveless Isolator, fully integrated, integrated air handling (work cell approach)**
- Processing of aseptic and high-potent micro batches
- Minimizing product loss (especially during start and end of production)
- Fast batch changes
- Complete batch-to-batch changeover within less than two hours

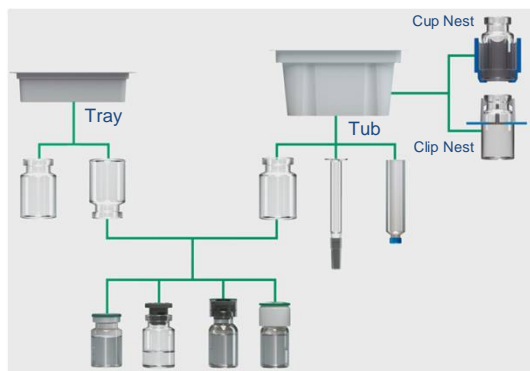


Joint development with



Gloveless isolator

Versynta microBatch



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2 Requirements & Expectations

Regulatory expectations.

FDA Guidance

The design of equipment used in aseptic processing should **limit the number and complexity of aseptic interventions by personnel.** (...) Automation of other process steps, including the **use of technologies** such as **robotics**, can further **reduce risk to the product.**



No aseptic interventions by personnel – even no set-up.



Instead, robotics will take over all main activities.

R. Friedman: “Use of robotics in aseptic processing has the potential to profoundly reduce contamination risks”

Source: FDA Guidance for Industry Sterile Drug Products, produced by aseptic processing cGMP, Sept. 2004

Presentation Ute Schleyer, Vetter and Klaus Ullherr Syntegon at ISPE Annual Meeting in Boston, Nov 1st 2021


Connecting Pharmaceutical Knowledge



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2 Requirements & Expectations

Regulatory expectations

Annex 1

So, what are we expecting?

Our expectation is that the contact parts (direct and indirect) are sterilized using a robust sterilization method that meets the current requirements of annex 1. This means that:

- the sterilizing agent reaches all of the critical surfaces in a consistent and repeatable manner, typically requiring processes such as moist or dry heat sterilisation.
- the item is unloaded from the sterilization process either wrapped in integral covering or container, or is transferred under grade A conditions, such as a transfer isolator into the manufacturing isolator.
- We also expect that the parts are not exposed to the isolator environment until the isolator has been closed and after completion of the work zone decontamination VHP cycle.

Source: Andrew Hopkins, MHRA Inspectorate Blog, commenting on EU Annex 1 draft




The steam sterilized equipment is unloaded into a H₂O₂ decontaminated grade A.



Unloading into a grade A environment, no VHP cycle after set-up!

Presentation Ute Schleyer, Vetter and Klaus Ullherr Syntegon at ISPE Annual Meeting in Boston, Nov 1st 2021


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Manufacturing Aspects

Regarding Filling, Finishing and Assembly

Rod insertion and labelling

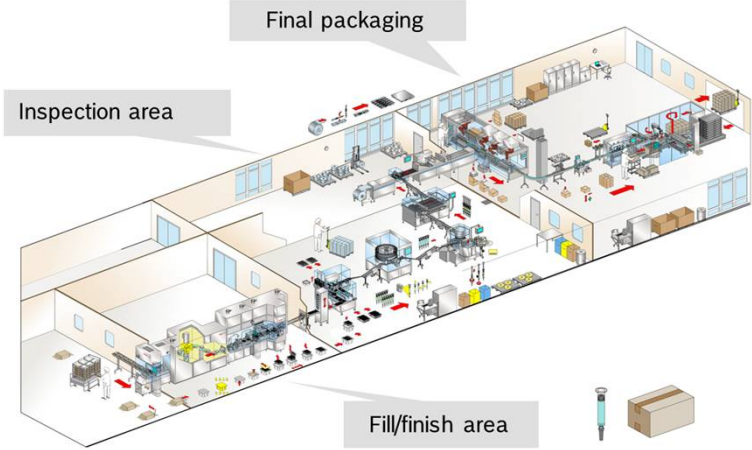
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Nested syringe processing



Final packaging

Inspection area

Fill/finish area

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Rod Insertion and Labeling



Video

Animation

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Summary



- There is a huge variety in filling and stoppering of syringes compared to e.g. vials
- The specific set-up is depending on the fill product and the syringe components
- Adapting the specific process of filling and stoppering on a production machine is quite challenging
- Interaction of containers/outer packaging and machine is crucial → collaboration between the manufacturers of syringes, plunger stoppers and machine builders is the key
- Bulk syringe processing is and will be an exception
- Processing nested syringes is state of the art
- More combi filling lines for small/medium batches (syringe, vial, cartridge)

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Questions?



Klaus Ullherr
Senior Product Manager

Syntegon Technology GmbH
Blaufelder Str. 45 • 74564 Crailsheim • Germany
Klaus.Ullherr@syntegon.com



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klaus.ullherr@syntegon.com



Klaus Ullherr, Senior Product Manager, Syntegon

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