

SX-310-RDL

Compact machine for automatic infeed, filling, and closing of injection vials.

Filling from 0.1 ÷ 250 ml / Filling system 100% weight control / Output up to 7,200 uph / Conforms with cGMP - US FDA

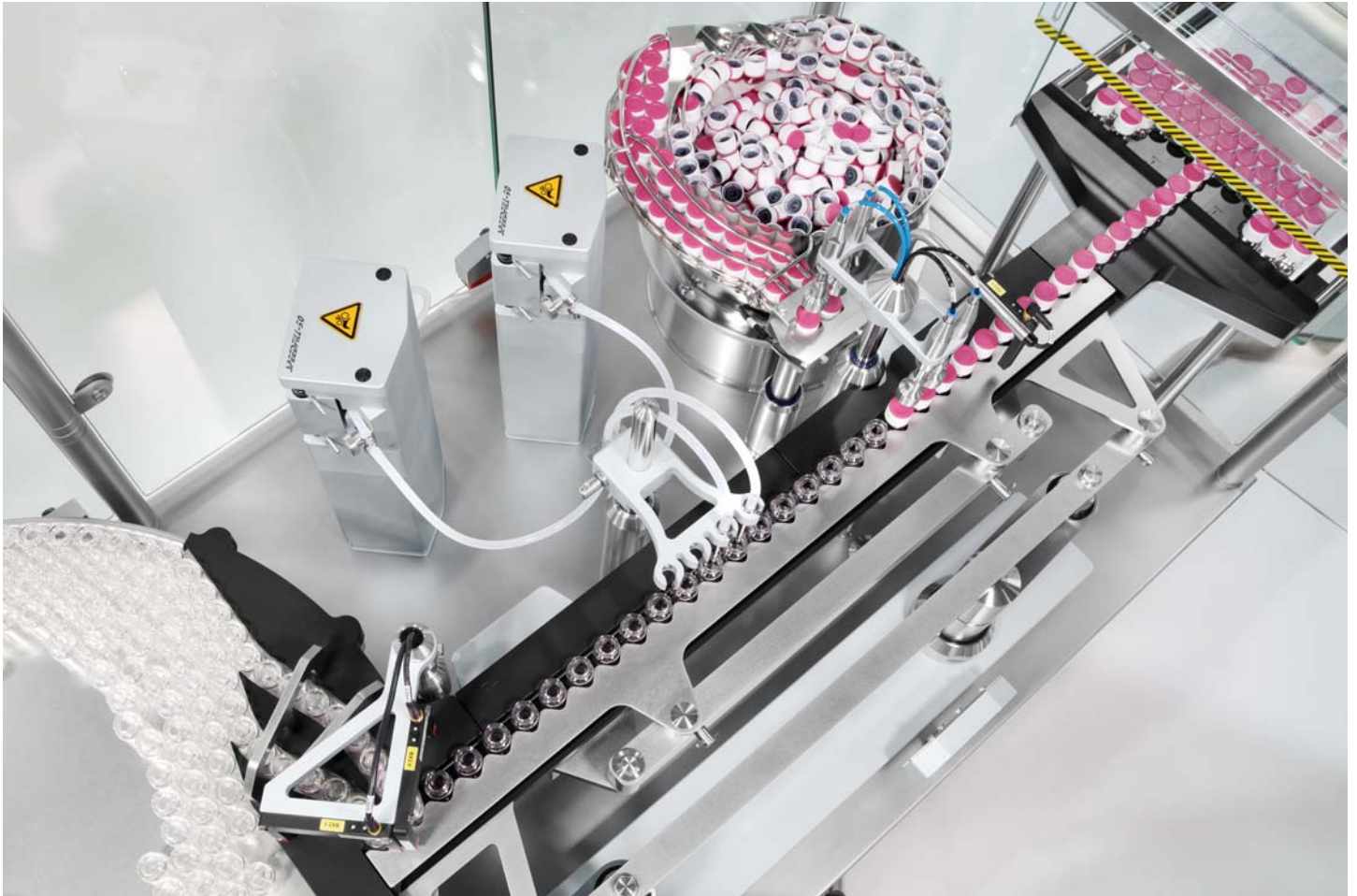
RayDyLy[®]



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Compact machine for automatic infeed, filling, and closing of injection and freeze-dried vials.

//// The equipment we present is a compact filling and closing machine for automatic processing of cylindrical vials in glass, plastic, or metal, for liquid, semisolid, and powder products, in sterile areas.

Suitable for RTU vials (ready to use) as well as for vials supplied in bulk.

The design has been made in compliance with the regulations of cGMP and US FDA, and in special accordance with the pharmaceutical, biotech, cosmetic, chemical and similar industries.

Output up to 7,200 uph.

The filling station can be equipped with valveless rotary piston pumps, made of stainless steel or ceramic, or with SpeedFill[®] peristaltic pumps for liquid products, and with vacuum-pressure fill guns for powders.

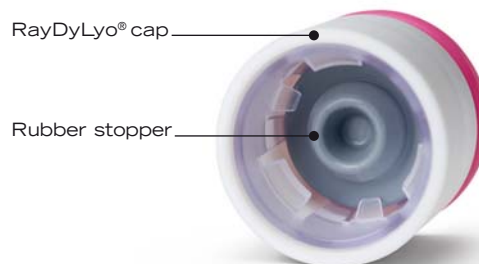
When using CIP / SIP construction elements, it is not necessary to remove the product contact parts for their cleaning or sterilization.



Allen Bradley or Siemens PLC.

RayDyLyo® caps offer multiple benefits:

- Elimination of crimping step for liquid and freeze-dried forms:
 - ✓ All-in-one solution: plastic cap and pre-assembled stopper. For ISO 8362-1 vials and ISO 8362-2 rubber stoppers.
 - ✓ Rubber stoppers are defined by the customer and pre-assembled automatically in the RayDyLyo® cap prior to the distribution on line.
 - ✓ Vial closure by simple vertical pressure.
 - ✓ Reduction of all risks of environmental contamination on the distribution lines.
 - ✓ Risk reduction of stoppers adhering to the freeze-dryer plates.
 - ✓ Reduction of “pop-off” effect.
 - ✓ Simplification and time-saving on freeze-drying operations.
- Wide range of caps:
 - ✓ Different possible diameters: 13/20 mm.
 - ✓ Closure system available in CTO (Central Tear-Off) and TTO (Total Tear-Off).
- Sterilization:
 - ✓ Choice of sterilization mode (Gamma or Autoclave).
- Ergonomics of the device:
 - ✓ Reduction of the efforts to remove the cap.
 - ✓ Reduction of risks of damaging gloves.



All dosing recipes can be saved and, therefore, can be later retrieved from the control panel. Production parameters, such as dosing volume or the kinematics of the filling system, are saved in the PLC. New recipes can be quickly and easily created.

For dosing volumes from 0.1 to 250 ml.

The pick & place station places the caps onto the vials, handling them by vacuum. Feeding of different caps is done automatically through AISI-316L vibrating feeders with electromechanical toolless fixation for easy change of format.

In order to work in sterile applications, DARA Pharma provide tailored solutions, such as LAF (Laminar Air Flow) and RABs (Restricted Access Barrier Systems). The generated vertical flow of sterile air ensures a permanent and reliable expulsion of particles and microorganisms from the working area.

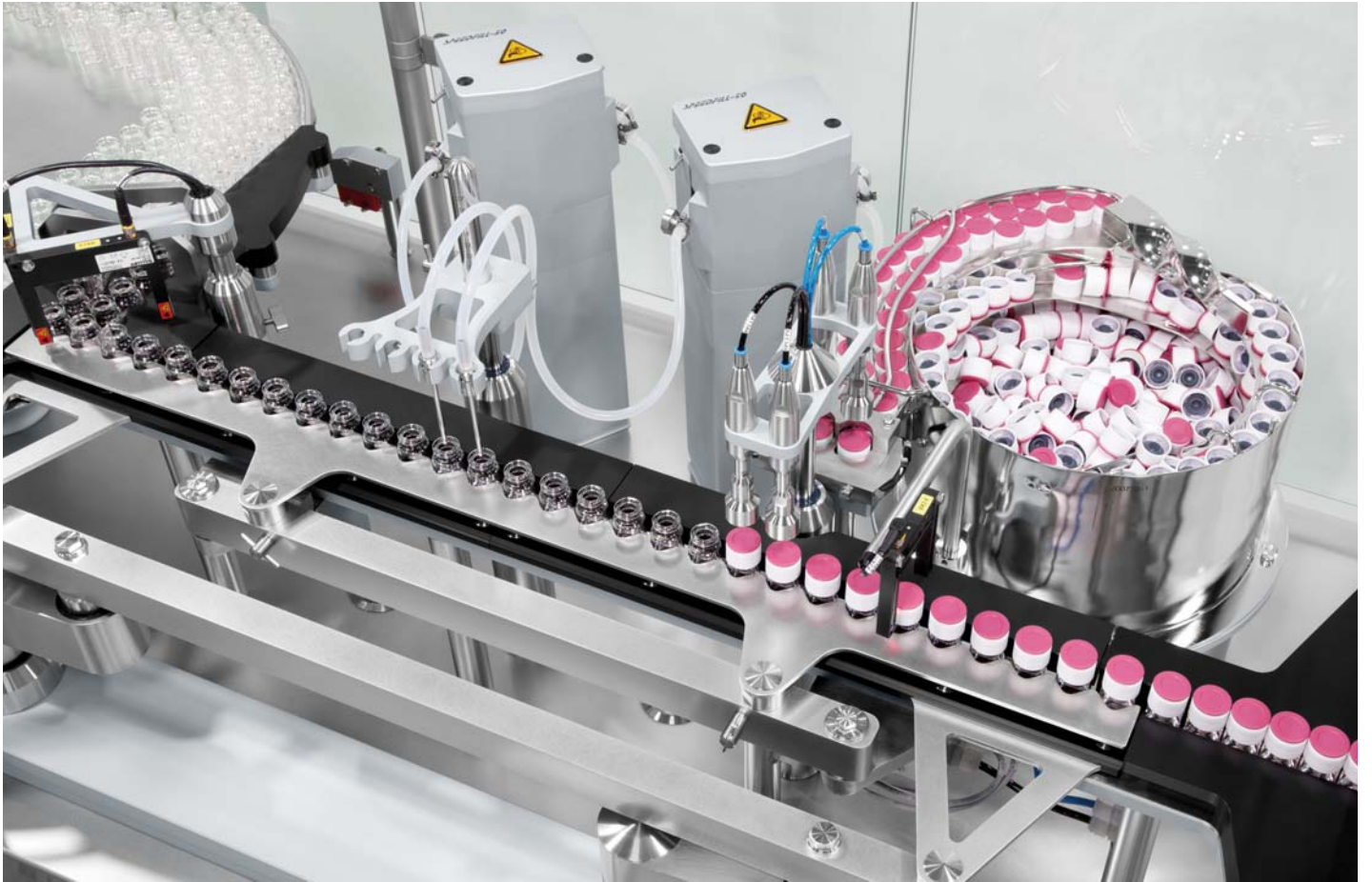
By using an isolator, the sterile area is reduced to the area of the filling and closing machine, that allows the equipment to operate in a clean room class D, complying with the regulations of the pharmaceutical industry.

Optional equipment:

- Washing unit and sterilization tunnel for vials supplied in bulk.
- Dosing control of 100% of processed vials through electronic weighing scales.
- Gas flushing before, during or after the filling process.
- Dosing system for CIP / SIP conditions.
- Vacuum-assisted positioning of caps to reduce the presence of oxygen in headspace.
- Automatic rejection of defective vials.
- Process data acquisition software in accordance with FDA 21CFR Part 11.
- Monitoring and particle counting.
- Vial output onto a double tray.
- Laminar flow unit / RABs / Isolator unit.
- IQ / OQ validation package.
- Printing / Codification.







Compact machine. The design is adapted to laminar flow conditions.

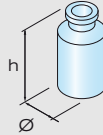



The pick & place station handles RayDyLy^o caps by vacuum.

SX-310-RDL

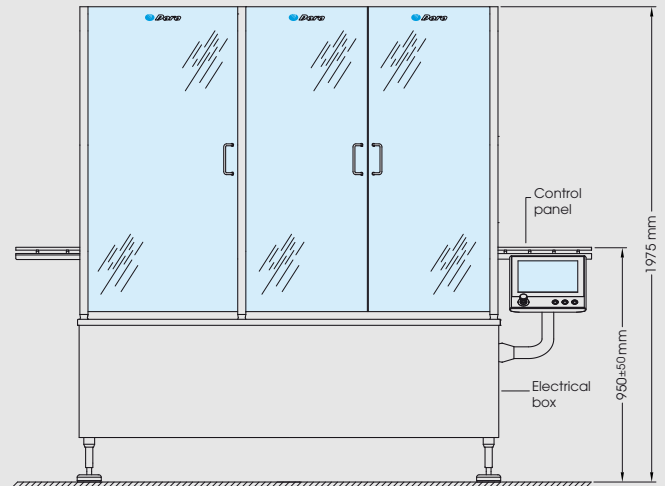
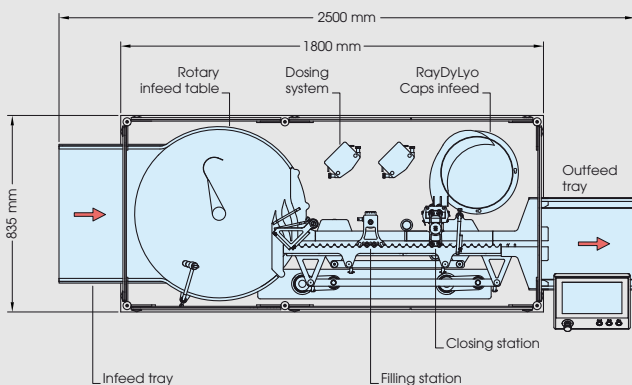
SX-310-RDL/S

SX-310-RDL/D

Max. output / uph:	3,600	7,200
Container dimensions:	 Ø 65 mm max. h 210 mm max.	Ø 36 mm max. h 75 mm max.
Filling product:	Liquid pharmaceuticals (solutions and suspensions)	
Type of closures:	RayDyLyo [®] cap Ø 13/20 mm	
Dosing range / accuracy:	0.1 ÷ 250 ml / ±0.5%	
Electrical supply:	230/400 VAC – 50/60 Hz – 3 kW max.	
Max. weight:	610 kg	720 kg
Materials:	AISI-304 stainless steel, anodised aluminum, POM and contact parts with product in AISI-316L stainless steel	
Format range:		

Environmental conditions: Temperature 5 ÷ 40 °C / Relative humidity 70% max. / Altitude 1,500 m max.

Dimensions: (*)



(*) SX-310-RDL/D version. Other configurations of the machine are possible.

Subject to technical modifications.

Please note that the illustrations may vary from the standard version in some details.