

NFL/2-RDL

Filling and closing machines for vials in nest and RayDyLyo[®] caps.

Compact machine / Filling and closing of vials in nest / Output up to 4,800 uph / Conforms with cGMP - US FDA

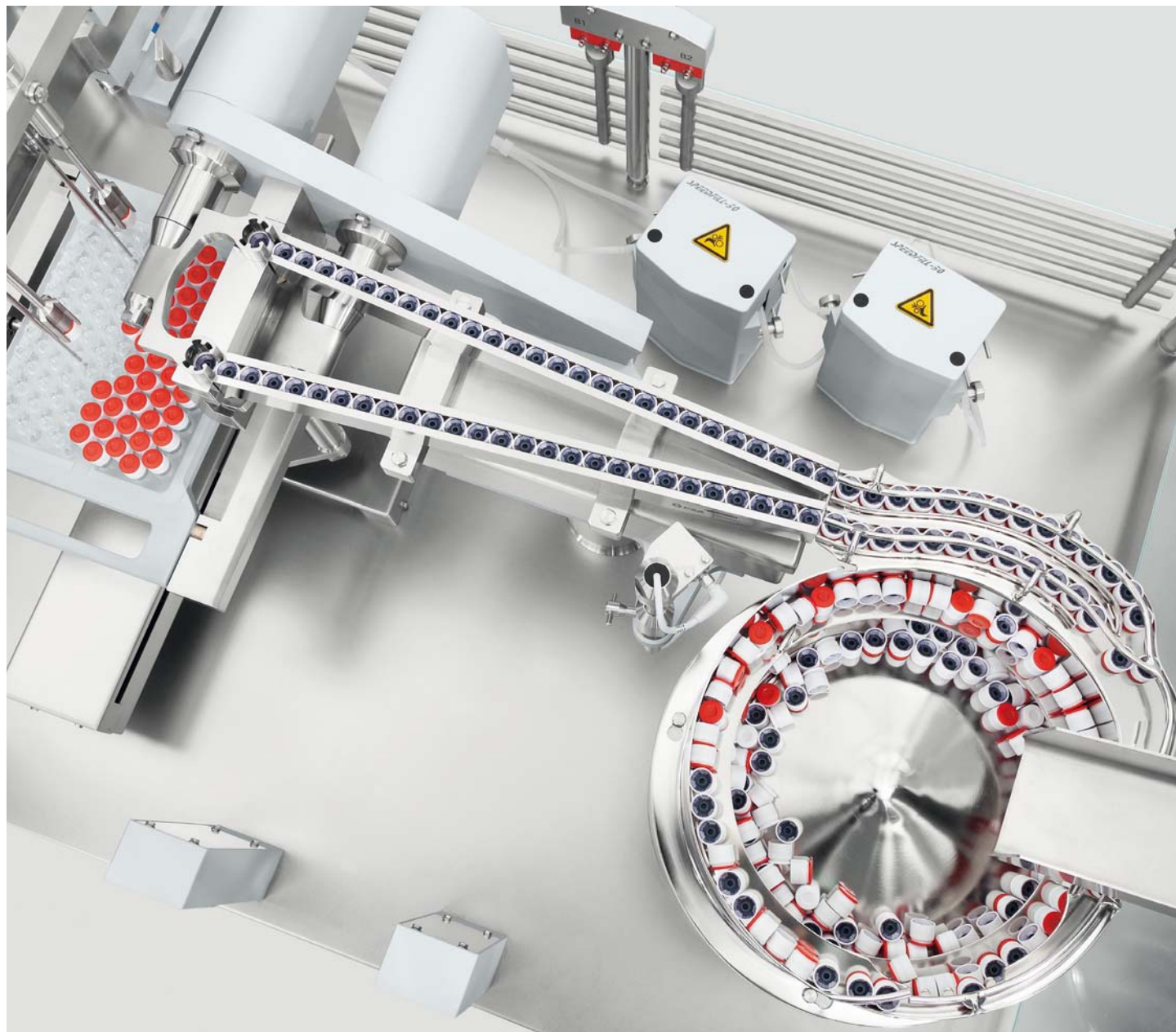


RayDyLyo[®]

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Compact machine to process RTU vials. Design adapted to work under laminar flow conditions.

//// Ready-to-use (RTU) containers remain an excellent choice in aseptic manufacturing.

The machine we present is a combination of filling and closing equipment to process RTU vials in nests. The vials are supplied ready-to-use, already sterilized and ready to be processed, therefore no washing, sterilization, or special transportation is required.

The design has been made for use in sterile areas, in compliance with cGMP and US FDA regulations, and in special accordance with the requirements of the

pharmaceutical and biotech industries.

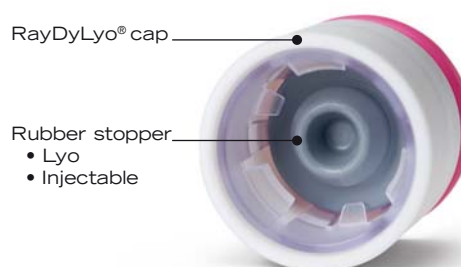
Production speed: up to 4,800 units per hour.

The filling station can be equipped with peristaltic pumps, model SpeedFill[®], for liquid products, valveless rotary pistons for semisolids, or powder doser.

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

RayDyLyo® caps offer multiple benefits for vial processing:

- Elimination of the crimping process for injectable 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 is available:
 - ✓ Diameters of 13/20 mm in different colors.
 - ✓ Closure system available in CTO (Central Tear-Off) and TTO (Total Tear-Off).



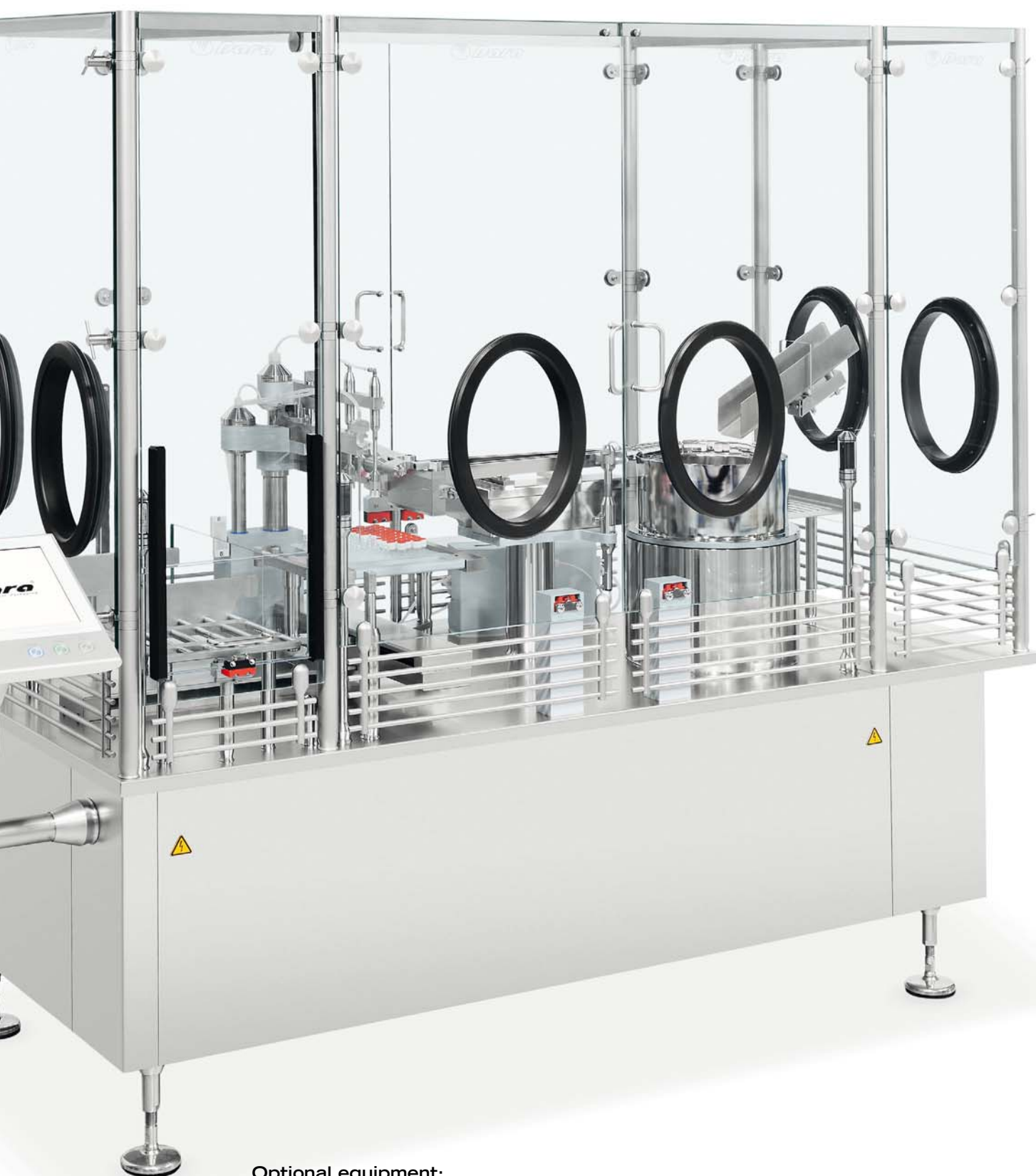
- Sterilization:
 - ✓ Different sterilization modes (Gamma or Autoclave).
- Ergonomics of the device:
 - ✓ Easy cap removal.
 - ✓ Reduction of risks of damaging gloves.

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.

With an integrated 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.



Feeding of different types of RayDyLyo® caps is done automatically, through AISI-316L vibrating feeders.



Optional equipment:

- Automatic debagging and delidding.
- Automatic loading and unloading of the nest.
- Vacuum-assisted positioning of caps to reduce the presence of oxygen in headspace.
- Gas flushing before, during or after the filling process.
- Dosing system for CIP / SIP conditions.
- Process data acquisition software in accordance with FDA 21CFR Part 11.
- Laminar flow unit.
- RABs / Isolator unit.
- IQ / OQ validation package.



RayDyLyo® caps with pre-assembled stoppers are transported inverted to avoid any contact with the product, ensuring aseptic conditions.

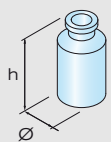


Filling and RayDyLyo® caps positioning on RTU vials.

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Max. output / uph: 4,800

Container dimensions:



Format	Ø	h	Ø cap	Vials per Nest
2R	16 mm	35 mm	13 mm	100/120
4R	16 mm	45 mm	13 mm	120
6R	22 mm	40 mm	20 mm	48
8R	22 mm	45 mm	20 mm	48
10R	24 mm	45 mm	20 mm	48
15R	24 mm	60 mm	20 mm	24
20R	30 mm	55 mm	20 mm	24
25R	30 mm	65 mm	20 mm	24
30R	30 mm	75 mm	20 mm	24

Filling product: Injectable liquid pharmaceuticals (solutions and suspensions)

Type of closures: RayDyLyo[®] cap Ø 13/20 mm

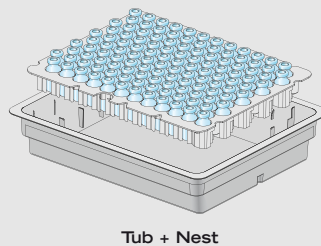
Dosing range / accuracy: 0,1 ÷ 30 ml / ±0,5%

Electrical supply: 230/400 VAC – 50/60 Hz – 7 kW max.

Max. weight: 1,100 kg

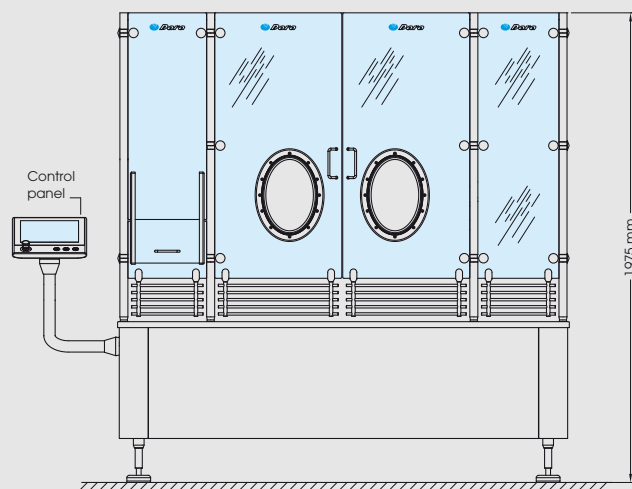
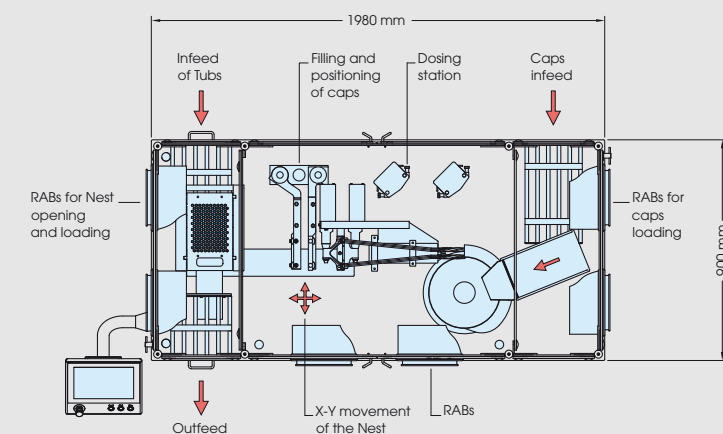
Materials: AISI-304 stainless steel, anodised aluminum, POM and contact parts with product in AISI-316L stainless steel

RTU format range:



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

Dimensions:



Subject to technical modifications.

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