

NFL/2-RDL

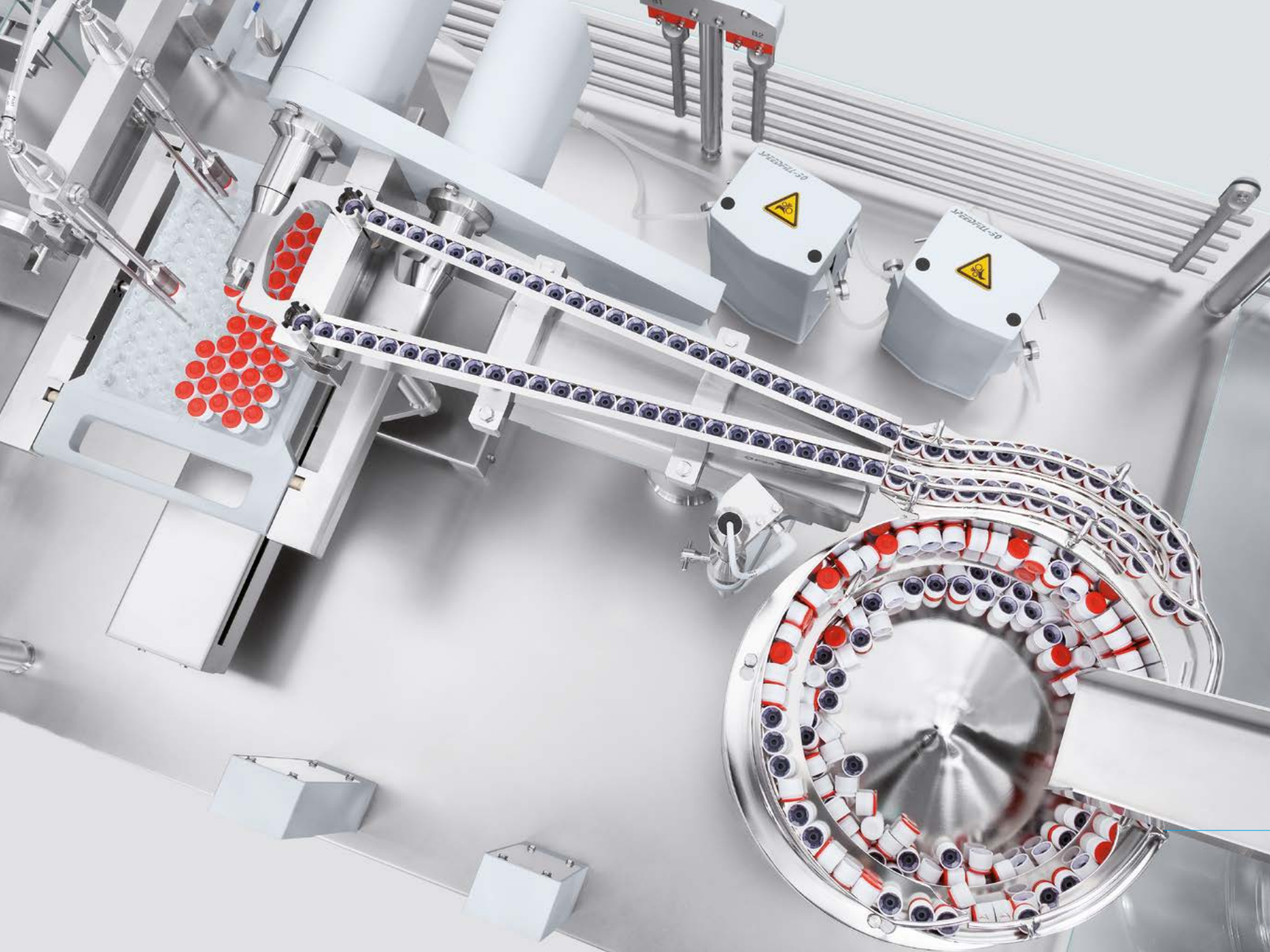
Filling and closing
machines for
vials in nest and
RayDyLyo® caps.



Vials in
Nest



RayDyLyo®



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



Liquid filling

NFL/2-RDL

Filling and closing machines for vials in nest and RayDyLy® caps.

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 a powder doser.

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

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

CLOSING

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 preassembled 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 freezedrying 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).

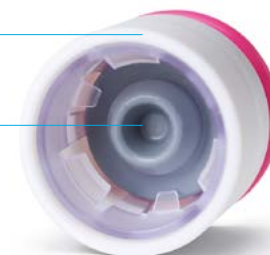
Ergonomics of the device:

- Easy cap removal.
- Reduction of risks of damaging gloves.

RayDyLyo® Cap

Rubber stopper

- Lyo
- Injectable



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



SpeedFill-50

2000/05-2

BX3.2



NFL/2-RDL

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.



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






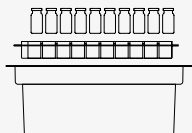


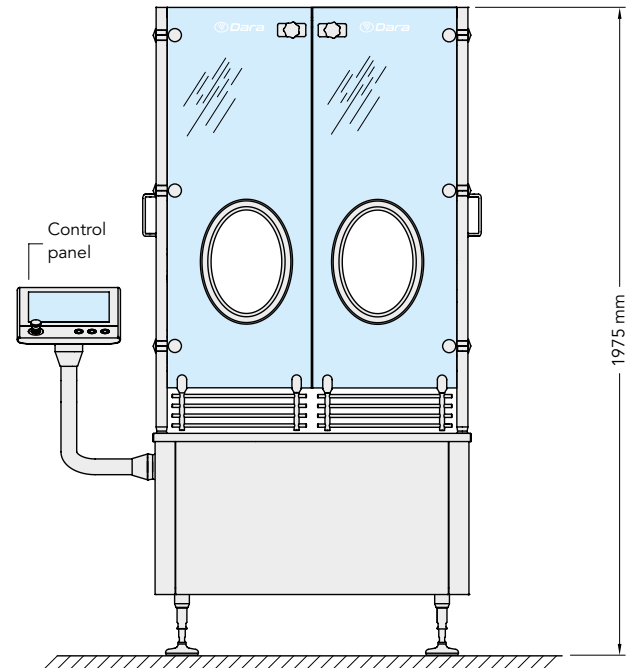
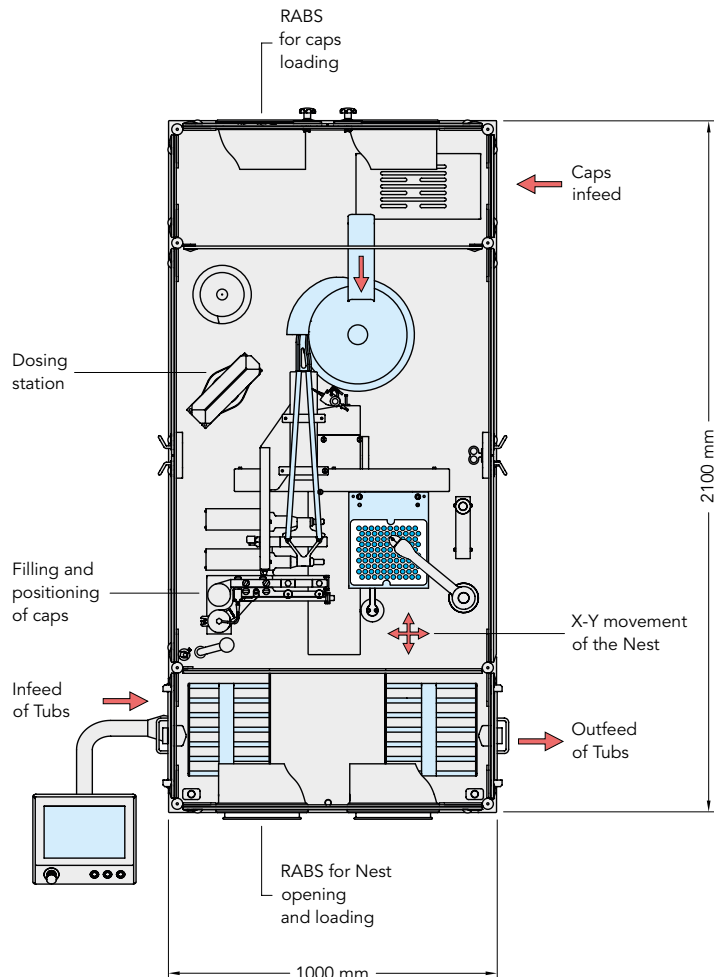
NFL/2-RDL

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 during filling and/or closing.
- 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.

*Filling and RayDyLyo® caps
positioning on RTU vials.*

Model	NFL/2-RDL				
Max. output / uph:	4.800 uph				
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				
Environmental conditions:	Temperature 5 ÷ 40 °C / Relative humidity 70% max. / Altitude 1,500 m max.				
Formats:	<div>  <p>RayDyLyo® cap with pre-assembled lyo stopper</p> </div> <div>  <p>RayDyLyo® cap with pre-assembled injectable stopper</p> </div> <div>  <p>Vials 2R ÷ 30R</p> </div> <div>  <p>Tub + Nest</p> </div>				



Subject to technical modifications.
Please note that the illustrations may vary from the standard version in some details.

Flexibility in motion



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