

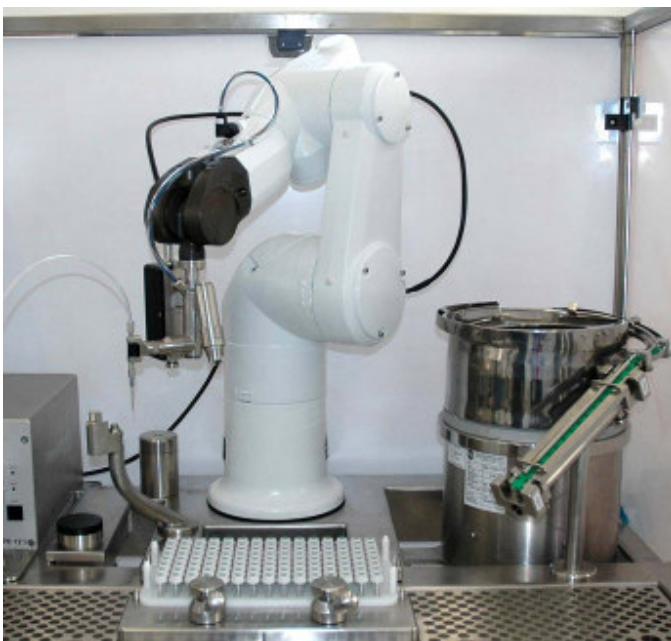
Aseptic TECHNOLOGIES

SAFER & EASIER aseptic filling



Crystal[®] Closed Vial Technology

■ ■ ■ *Laboratory Crystal[®] L1 Robot Line*



Enables **Safer & Easier** aseptic filling operations.

Designed to fill ready-to-fill polymer vials with:

- Research lots,
- Clinical and stability batches,
- Commercial batches for niche products.

Liquid and lyophilized products.

Nominal capacity up to **600** Closed Vials per hour.

Philosophy and process

The **Crystal[®]** technology is based on the concept that the polymer vials are provided clean (molded in ISO5 clean room), already closed (stopper in place and secured) and sterile (gamma-irradiated), i.e. **ready-to-fill**.

The Laboratory **Crystal[®] L1** Robot Line has been developed to meet small scale pharmaceutical filling with a filling capacity going up to 600 vials/hour. Typical batch size ranges from a few hundred up to 5,000 vials, on a single shift basis.

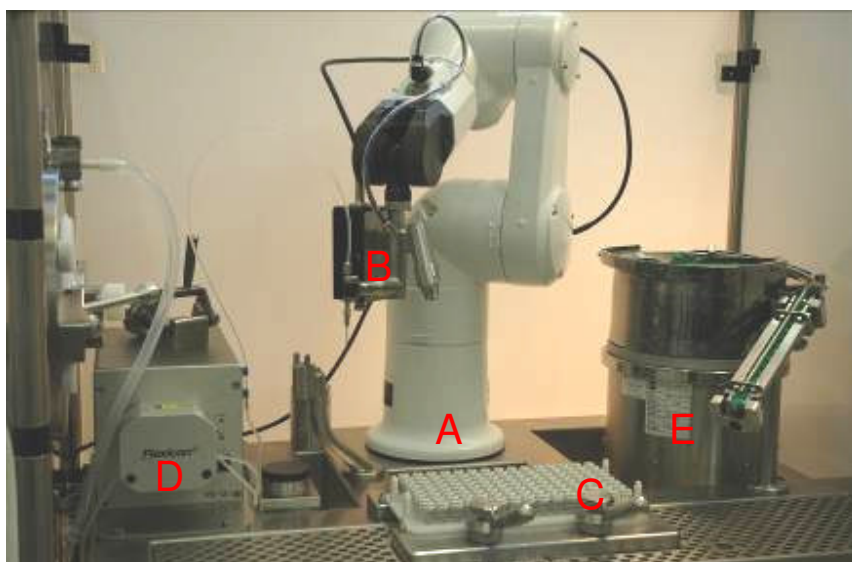
Fully compliant with cGMP requirements, the Laboratory **Crystal[®] L1** Robot Line is able to process all ready-to-fill **Crystal[®]** Closed Vials (from 1 to 50 ml). Vial format change is easily done by program selection on HMI. Only 1ml format requires few simple part changes.

The complete process is made of the following steps:

1. Manual positioning and locking of a rack with vials on the operation area
2. Filling performed by a specially designed needle that pierces the stopper, dispenses the liquid, and comes out by lifting
3. Laser resealing of the puncture trace by a laser shot on the stopper surface
4. Capping performed inside the barrier, by simple snap-fit of plastic cap.
5. Manual unloading of the vial rack.

Filling, laser re-sealing and capping are performed by a specially designed 6-axe clean room robot with multi-task head.

- A. 6-axe robot
- B. Multi-task head
- C. Vial rack on its locking base
- D. Pump
- E. Cap vibrating bowl



Quick facts

Laboratory Crystal [®] L1 Robot Line	
Applications	Aseptic filling of liquid and freeze-dried parenterals. All types of products (including cytotoxics and biohazard).
Output (2ml vials)	Up to 600 vials/hour.
Filling volume	0.1 ml to 50 ml + overfill.
Filling accuracy	+/- 1% (+/-10 µl for small volumes below 1 ml).
Dimensions (L x W x H, in mm)	1190 x 760 x 930 (core equipment without containment).
Utilities	Electricity, no water, no compressed air.
Materials	AISI 316L for product contact parts.

Aseptic Technologies S.A. reserves the right to make any changes to the described machine characteristics without notice.

Versions

Upon your project specifications, the Laboratory **Crystal**[®] L1 Robot Line can be provided in various versions:

- **Containment**
 - As a sub-system, to be installed in a third party barrier (e.g. existing or new isolator);
 - Equipped with a safety barrier, to prevent operator presence in the filling area during operations;
 - In a CVFS¹ with glove access into the filling area;
 - In an isolator/closed CVFS+ (allowing washing, for highly potent products) with glove access into the filling area;
 - In an isolator/closed CVFS++ (allowing washing and decontamination, for biohazard products) with glove access into the filling area.

- **Material entry/exit systems**
 - Mousehole;
 - RTP (Rapid Transfer Port), via beta-bags;
 - VHP (Vaporized Hydrogen Peroxide) airlock.

- **Vial formats**
 - Closed Vials only (1 to 50 ml);
 - Closed Vials and open plastic & glass vials.

¹ “CVFS - Closed Vial Filling System” is defined as “An aseptic filling system providing an environment achieving uncompromised Class ISO 5 protection that surrounds containers which are delivered closed and sterile inside, are filled through their stoppers and then immediately re-sealed to preclude the possibility of microbial ingress”.

Overview of *Crystal*[®] line range

	<i>Crystal</i> [®] M1 Filling Station	<i>Crystal</i> [®] L1 Robot Line	<i>Crystal</i> [®] Cx Filling Line	<i>Crystal</i> [®] PX Filling Line	<i>Crystal</i> [®] Pxx Filling Line
Max. output (1ml)	180 v/h	600 v/h.	4.500 v/h	9.000 v/h	36.000 v/h
Applications	Aseptic filling	Aseptic filling, Aseptic-toxic, Biohazard	Aseptic filling	Aseptic filling, Aseptic-toxic, Biohazard	Aseptic filling
Freeze drying	YES	YES	YES	YES	-
Filling volume	0.1 ml to 50 ml + overfill.	0.1 ml to 50 ml + overfill.	0.1 ml to 50 ml + overfill.	0.1 ml to 50 ml + overfill.	0.1 ml to 50 ml + overfill.
Containment	ISO-5 in ISO-8 or isolator	ISO-5 in ISO-8 or isolator	ISO-5 in ISO-8	ISO-5 in ISO-8 or isolator	ISO-5 in ISO-8
Typical footprint	1 m ²	1,5 m ²	9 m ²	16 m ²	44 m ²
Utilities	Electricity, no water, no compres. air	Electricity, no water, no compres. air	Electricity, no water, no compres. air	Electricity, no water, no compres. air	Electricity, compres. air, no water.

Overview of *Crystal*[®] vial range



<i>CVFL</i> [®] Vials	1 ml	2 ml	6 ml	10 ml	20 ml	50 ml
Height (in mm., with /without cap)	33.1/34.1	33.1/34.1	39.3/40.3	49.8/50.8	61.2/62.2	84.9/85.9
Stopper upper diameter (in mm.)	8	9	9	9	9	9
External vial diameter (in mm.)	18.3	22.3	25	25	30	36
Maximum volume filled (in ml.)	1.35	2.25	7.6	11.7	21.8	52.1
Freeze-drying	Yes, every Closed Vial format can be lyophilized*					
Oxygen-depleted	Yes, every Closed Vial format can be delivered with very low O ₂ content*					
Light-sensitive	Yes, every Closed Vial format is available with amber body					
Colored caps	Caps and rings are available in different colors for differentiation					

* Protective packaging against permeability required as for all semi-permeable containers

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