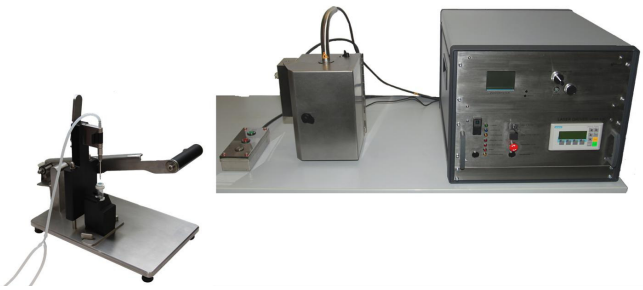
Aseptic TECHNOLOGIES

SAFER & EASIER aseptic filling

Crystal® Closed Vial Technology

Laboratory Crystal® M1 Filling Station



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.

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***.

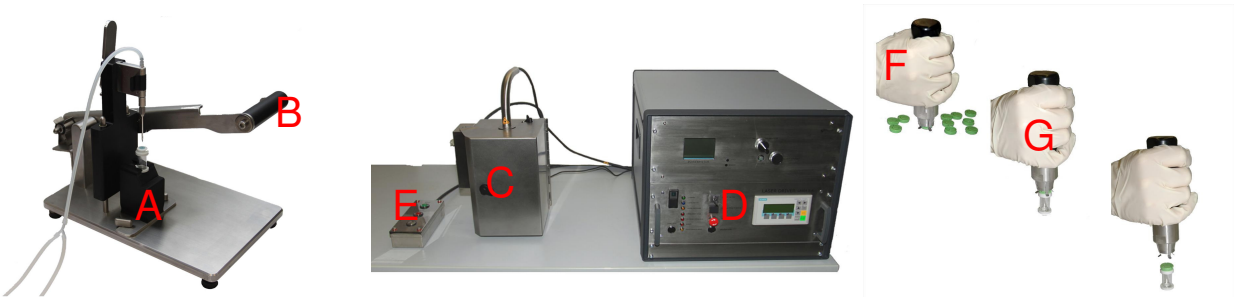
The Laboratory ***Crystal® M1*** Filling Station has been developed to meet small scale pharmaceutical filling. Being manually activated, the filling capacity depends on operator capabilities, with batch size ranging from a few up to 1,500 vials (two operators), on a single shift basis.

Fully compliant with cGMP requirements, the Laboratory ***Crystal® M1*** Filling Station is able to process all sizes of ready-to-fill ***Crystal®*** Closed Vials (from 1 to 50 ml) thanks to a single format part: the vial supporting base.

The complete system is intended for operation in ISO5 conditions, type of containment according to specific product requirements.

The full process is made of the following steps:

1. Filling
   - The vial is placed manually on its supporting base (A);
   - Piercing of the stopper is accurately achieved (stroke and centering) by simple action on the lever (B);
   - Filling is performed with e.g. a peristaltic pump before needle withdrawal.
2. Laser re-sealing
   - The vial is manually transferred into the laser safety cabinet (C);
   - The laser control unit (D), being installed outside the ISO5 containment, is activated via the remote controller (E) located inside the containment;
   - The puncture trace is re-sealed by a laser shot on the stopper surface.
3. Capping is performed by simple snap-fit of a plastic cap (F and G).



Quick facts

Crystal® M1 Filling Station	
Applications	Aseptic filling of liquid and freeze-dried parenterals. All types of products.
Output (2ml vials)	Manual operations, can reach up to 1,500 vials per shift.
Filling volume	0.1 ml to 50 ml + overfill.
Filling accuracy	Typically 1%, depends on filling pump selected.
Dimensions	Core equipment is easily placed inside a classical cabinet.
Utilities	Electricity only, 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

The Laboratory ***Crystal® M1*** Filling Station can be installed in various types of containment:

- ***Containment systems***
  - Bio Safety Cabinet (BSC);
  - Iaminar airflow (LAF) cabinet with glove access into the filling area;
  - isolator.

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

Upgrade capability

Following capacity need increase, the Laboratory ***Crystal® M1*** Filling Station can be easily upgraded to the Laboratory ***Crystal® L1*** Robot line, the complete laser chain being re-used.

Overview of *Crystal®* line range

	Crystal® M1 Filling Station	***Crystal® L1*** Robot Line	***Crystal® Cx*** Filling Line	***Crystal® PX*** Filling Line	***Crystal® 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 IS0-8 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	13 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

1 ml 2 ml 6 ml 10 ml 20 ml 50 ml

CVFL® 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

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

Aseptic Technologies S.A.

www.aseptictech.com
info@aseptictech.com
+32 81 409 410

rue Camille Hubert 7
B-5032 Gembloux
BELGIUM