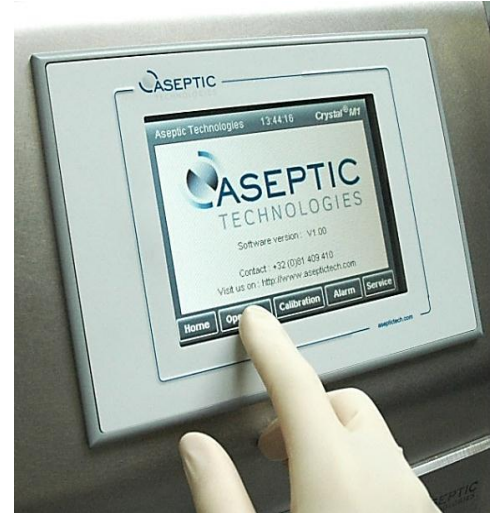


Crystal[®] M1 Filling Station

Optimized for batch size ranging from a few up to 1,500 vials, the *Crystal[®] M1 Filling Station* is designed to fill research lots, stability batches and niche commercial products.



Process

Filling

- The ready-to-fill AT-Closed Vial[®] is placed manually on its supporting base.
- Piercing of the stopper is accurately achieved by simple action on the lever. Filling is performed using a peristaltic pump before needle withdrawal.

Laser re-sealing

- The vial is manually transferred into the laser safety cabinet. The laser control unit, installed outside the ISO5 containment, is activated via the embedded remote.
- The puncture trace is re-sealed by a 1 second laser shot on the stopper surface.

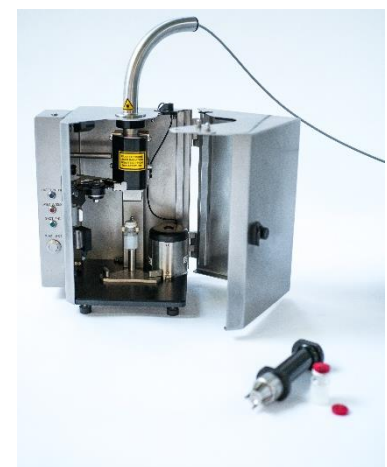
Capping

Performed by simple snap-fit of a plastic cap

Versions

The *Crystal[®] M1 Filling Station* can be installed in following types of containment with various features:

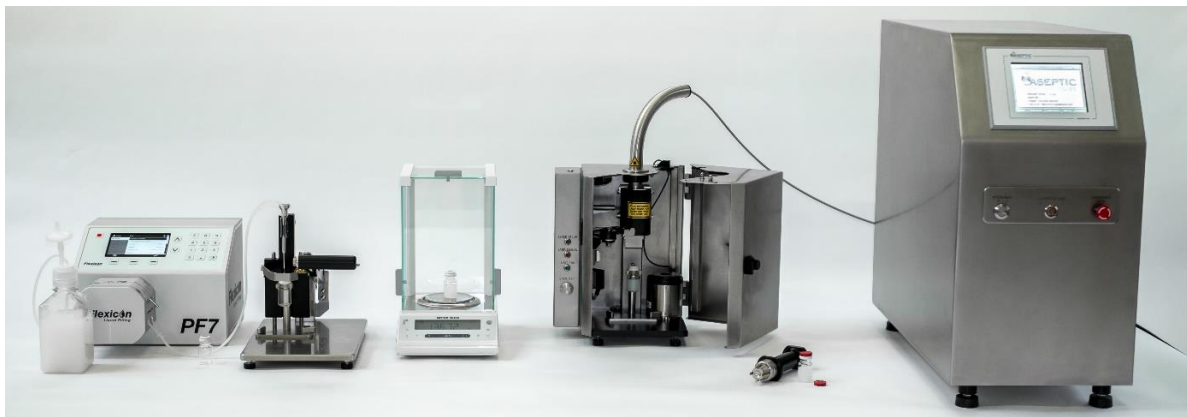
- Bio Safety Cabinet (BSC);
- Existing Isolator.



A separate integrated equipment *Crystal[®] Pure M1* is available for manual filling under isolator.

Crystal[®] M1 Filling Station : Specification

Applications	Aseptic filling of liquid parenterals, including
	- Autologous and allogeneic cell therapy, gene therapy;
	- Intermediate products for cell and gene therapy;
	- Immunotherapies;
	- Hospital pharmacy preparations;
	- Individualized or small batch production.
Output (2ml vials)	Manual operations, up to 1,500 vials per shift (*).
Filling volume	0.1 ml to 50 ml.
Filling accuracy	Typically, 1% (over 1 ml, for water-like viscosity product).
Dimensions	Core equipment is easily placed inside a biological safety cabinet or an isolator.
Utilities	Electricity only. No water, no compressed air.
Product Path	All single-use.
Materials	Compatible with classical sanitizing agents, H ₂ O ₂ decontamination.



Optional features

- Peristaltic dispensing pump;
- Foot switch for the pump;
- High precision balance.

Cleaning

The exposed surfaces of the filling tool, the laser housing and the capping tool are made of stainless steel and polymer materials compatible with classical sanitizing agents and H₂O₂ decontamination.

Validation package

The Crystal[®] M1 Filling Station is delivered with a full Validation Master Plan of the AT-Closed Vial[®]. The table of content is available on our website in the chapter Compliance > Validation > AT-Closed Vial[®] Technology.