



Crystal M1

Small batch filling station

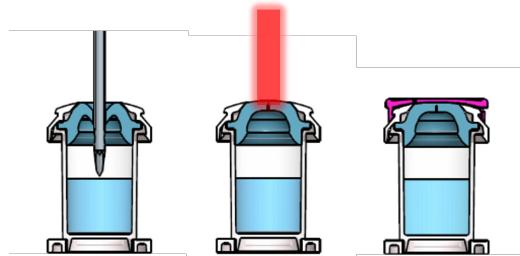
The Crystal M1 Filling Station is a tabletop aseptic filling system for the AT-Closed Vial® Technology, de-risking operations and ideal for small GMP batches.

Crystal M1 – Small batch filling station

Process

The AT-Closed Vial® is filled in three simple steps.

- Filling: The vial is filled through the stopper with a specialized sterile needle. Once the needle is withdrawn, the stopper re-closes mechanically as a result of its elastic properties
- Laser re-sealing: The stopper is resealed with a one second laser shot
- Capping: The sterile snap-fit cap is placed on the vial to maintain stopper protection up to the point of product collection



Ideal for small batches

- Adapted to very small batches
- Up to a couple hundreds of vials per batch

Off-the-shelf

- Easy to validate & deploy
- At your site in 6 weeks
- Installed and qualified in one day

Quick and simple batch-to-batch changeover

- Single-use and sterile product-contact parts
- No cleaning validation required

Compact and flexible system

- Tabletop design that can be installed inside a BSC, RABS or SKAN isolator, giving flexibility to accommodate different containment environments

Specifications

Application	Aseptic fill & finish
Vial sizes	1 mL, 2 mL, 6 mL, 10 mL, 20 mL, 50 mL
Filling accuracy	± 2%
Batch size	Up to 150 vials per hour (two operators)
Materials compatibility	Resistant to classical cleaning agents
Product path	Single-use materials for product contact parts
Included equipment	Filling tool, laser housing, capping tool, laser control unit
Optional equipment	Peristaltic dispensing pump, foot switch for the pump, high precision balance
Electrical supply	Standard 110/230 V (to be selected at order), AC earthed
Cabinet dimensions (recommended)	180 x 60 cm (6 x 2 ft.)
Operating temperature	18 to 22°C (64.4 to 71.6°F)
Environment	Adapted for cleanroom and GMP-compliant environments
Warranty	12 months, starting from FAT date
Documentation	English manuals + LOD, engineering, validation, certificates, shipping list
Packaging	Air- and road-ready cardboard boxes
Validation	FAT per AT standards, FAT consumables included, VMP for AT-Closed Vial® included
Compliance	European technical standards, Standards and recommendations of the International Electrotechnical Commission (IEC) and EN 12626 and EN 60825 for the laser technology
Training	On-site training on day of installation

