

# Small batch Filling Station for R&D and niche commercialized products

Optimized for small batches, the Crystal™ M1 Filling Station is a tabletop aseptic filling system, derisking your manual fill & finish operation.



## Manage your production in house

The Crystal™ M1 Filling Station is a manual laboratory equipment. Available in 6 weeks, installed and qualified in one day, you can quickly and safely engage in fill & finish processes without relying on external entities.

## Choose adaptivity

The Crystal™ M1 Filling Station can easily adapt to your needs. From R&D to early phase clinical development, we will guarantee that your fill & finish process satisfies all applicable standards.

## Ensure the safety of your process

Together with the AT-Closed Vial® technology, the Crystal™ M1 Filling Station ensures contamination management as the AT-Closed Vial® remains functionally closed throughout the filling process.

## Think about the future

At Aseptic Technologies, we are always one step ahead. We have designed the Crystal™ M1 Filling Station as an equipment that will help you easily scale out your production. Our robotic Filling Lines will also allow you to scale up your manufacturing. We will be with you all along, ready to collaborate on customized solutions to best fit your needs.

# Satisfying the needs of small batch processing

The Crystal™ M1 is used for aseptic filling of liquid parenterals. Perfect for small production, it presents the following characteristics:

- Up to 150 AT-Closed Vial® per hour
- 0,1 ml to 50 ml filling
- High filling accuracy
- At your site in 6 weeks
- Installed and qualified in 1 day
- Easy validation
- For installation in a standard biosafety cabinet or an isolator
- Single-use materials for product contact parts
- Toolless format change



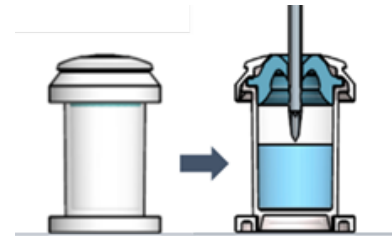
# Enabling

## Quick, safe and easy fill & finish

The Crystal™ M1 Filling Station is an easy-to-use manual filling equipment. In just three steps, you can fill the AT-Closed Vial®.

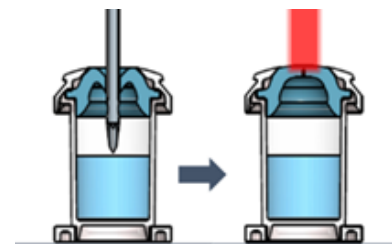
### 1. Filling

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



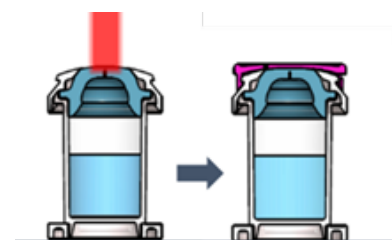
### 2. Laser re-sealing

- 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.



### 3. Capping

- Performed by simple snap-fit of a plastic cap.
- Facilitated by the use of the AT-EasyCap™.



# Adapting to the environment requirements

## Containment

The Crystal™ M1 Filling Station can be installed in the following types of containment:

- Biosafety Cabinet (BSC)
- Isolator
  - The integrated equipment M1 for Pure is available for manual filling under SKAN Pure isolator.
  - The integrated equipment M1 for Spectra is available for manual filling under SKAN Spectra isolator.

## Features

Several optional features are available to ease your manual filling process:

- 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 316L stainless steel and polymer materials (Polyoxymethylene, POM), which are compatible with classical sanitizing agents and H<sub>2</sub>O<sub>2</sub> decontamination.

# Our quality engagements

## Validation Master Plan

The Crystal™ M1 Filling Station is delivered with a full Validation Master Plan, together with all validation tests of the AT-Closed Vial®.

## Aseptic Technologies certifications

- ISO 9001:2015: Quality management systems
- ISO 15378:2017: Primary packaging materials for medicinal products

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