

## AT-Closed Vial®



### CONCEPT

The **AT-Closed Vial® Technology** is based on the concept of the ready-to-fill Closed Vial, whereby polymer vials are provided:

- clean (molded in ISO5 clean room);
- already closed (stopper in place and secured);
- sterilized (gamma-irradiated).

### MATERIALS

Materials selected for the product contact parts meet USP and EP requirements for pharmaceutical primary container:

- COC (Cyclo-Olefin Co-polymer) for vial body;
- TPE (Thermo Plastic Elastomer) for stopper.

### FIELDS OF USE



#### Biological

Vaccines  
mAbs  
RNA/DNA-based products

Low leachable profile, twice less particles than in glass vial



#### Potent

Cytotoxics  
Radiopharmaceuticals  
Nanomedicines

Unbreakable container, always closed to avoid contamination



#### Cryostored

Cell therapy  
Gene therapy  
Other low T° storage products

Container Closure Integrity even in liquid nitrogen



AT-Closed Vial®	1 ml	2 ml	6 ml	10 ml	20 ml	50 ml
Height (in mm, +1mm if capped)	33.10	33.10	39.30	49.80	61.20	84.90
External vial diameter (in mm)	18.30	22.30	25.00	25.00	30.00	36.00
Maximum volume filled (in ml)	1.35	2.25	7.60	11.70	21.80	52.10
Cryogenic storage	can be cryopreserved while keeping Container Closure Integrity					
Colored caps	are available in different colors for product differentiation					

Specific solutions for UV-, O<sub>2</sub>-sensitive, lyophilized products can be offered.

# Crystal<sup>®</sup> Filling Lines



## PROCESS

The overall filling process of the ready-to-fill AT-Closed Vials<sup>®</sup> is made of very few steps:

1. **Filling:** the stopper is pierced by a specially designed needle dispensing the product inside the container;
2. **Closing:** the puncture trace is re-sealed by a laser shot on the stopper;
3. **Capping:** simple snap-fit of plastic cap, inside the barrier.

## SCALING-UP

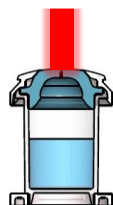
Straightforward scaling-up: identical processing, tools and disposables are used at all capacity levels.

## VALIDATION

To support the approval of your products, complete Validation Master Plan (VMP) is provided with every Crystal<sup>®</sup> Filling Line.



Ready-to-fill AT-Closed Vial<sup>®</sup>



3 process steps: filling, laser re-sealing, capping



Filled AT-Closed Vial<sup>®</sup>

	Crystal <sup>®</sup> M1 Filling Station	Crystal <sup>®</sup> L1 Robot Line	Crystal <sup>®</sup> SL1 Robot Line	Crystal <sup>®</sup> PX Filling Line
Container	AT-Closed Vial <sup>®</sup>	AT-Closed Vial <sup>®</sup>	AT-Closed Vial <sup>®</sup> , Prefilled Syringe, Open Glass Vial <sup>(1)</sup>	AT-Closed Vial <sup>®</sup>
Max. output	180 u/h	600 u/h	600-700 u/h	6.000-10.800 u/h
Containment	BSC or Isolator	RABS or Isolator	RABS or Isolator	RABS or Isolator
Typical footprint	1 m <sup>2</sup> 11 ft <sup>2</sup>	1,5 m <sup>2</sup> 16 ft <sup>2</sup>	1,5 m <sup>2</sup> 16 ft <sup>2</sup>	12-18 m <sup>2</sup> 130-195 ft <sup>2</sup>
Closing IPC	100%	100%	100%	100%
Utilities	WFI: Vacuum: Electricity:	- - Yes	- Yes Yes	- - Yes



More information available on [www.aseptictech.com](http://www.aseptictech.com)

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

(1) Ready-to-fill nested containers.