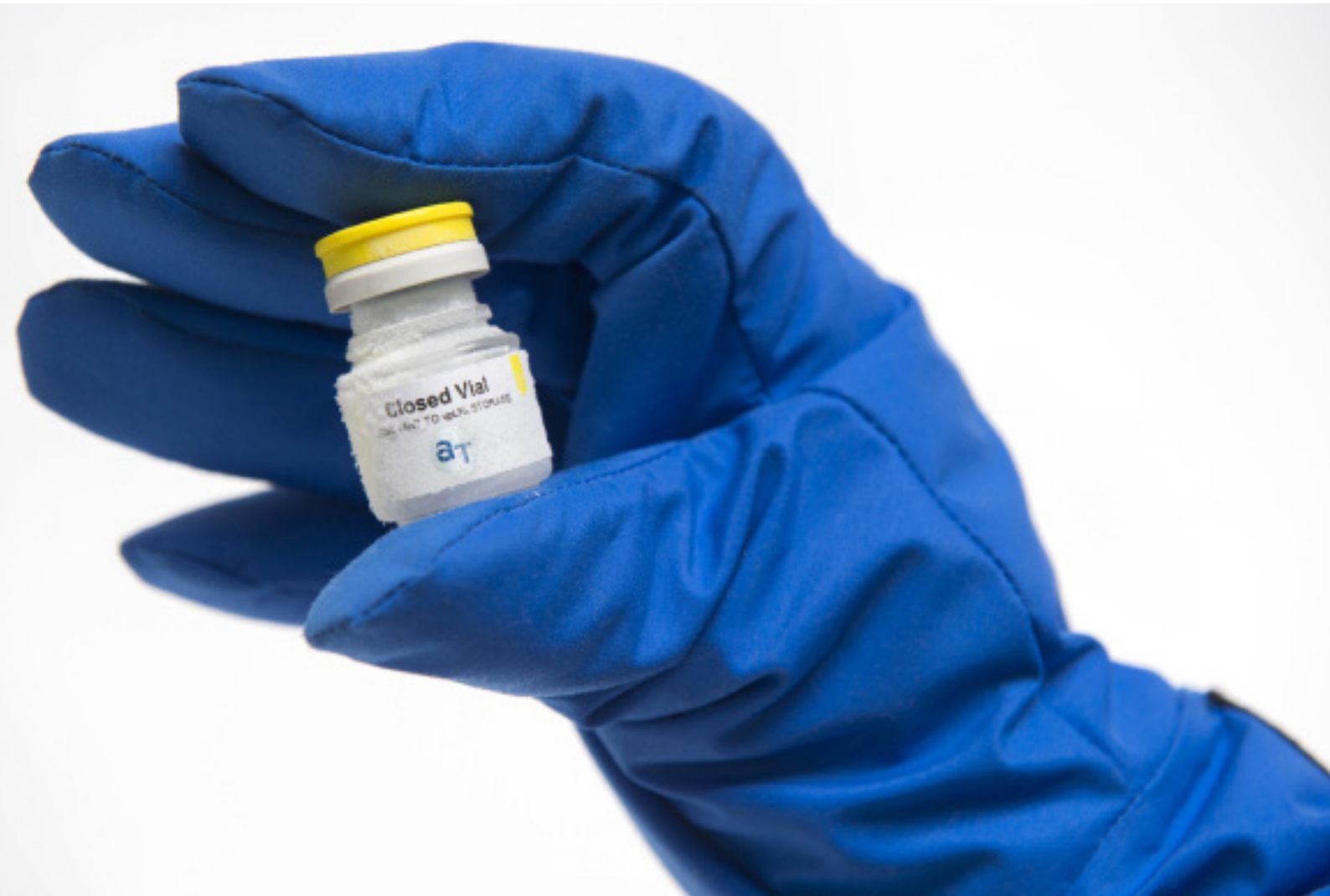
aSEPTIC TECHNOLOGIES

AT-Closed Vial®

Ready-to-fill closed vial



Ready-to-fill
Closed vial for aseptic fill & finish

The AT-Closed Vial® technology is based on the concept of a ready-to-fill closed vial, reducing the risk of contamination of the filling process. The AT-Closed Vial® is

- ⟶ Clean: low level of particles as a result of molding in ISO5 cleanroom
- ⟶ Closed: vial body and stopper assembled right after molding, in ISO5
- ⟶ Sterile: ready to use after gamma irradiation

Container Closure Integrity

The AT-Closed Vial® technology enables safe cryogenic storage of the injectable drug product and its intermediate GMP-grade products.

The robustness of the container closure integrity (CCI) in cryogenic temperatures is validated and ensured by the vial design, the materials and manufacturing process, and the AT-Closed Vial® filling process.

Perfect for cell & gene therapies

Since 2009, the AT-Closed Vial® technology has been the solution of choice for autologous and allogeneic cell and gene therapies, viral vectors, and cell banks. It is trusted by biotech and pharmaceutical companies, academic institutions, CDMOs and hospitals globally.

Adapted design
for safety and choice

Safe materials

The product contact parts are made of the following materials:

- ⟶ Vial body: Cyclo-Olefin Copolymer (COC)
- ⟶ Stopper: Thermoplastic Elastomer (TPE)

The AT-Closed Vial® meets USP and EP requirements for pharmaceutical primary containers.

Vial range

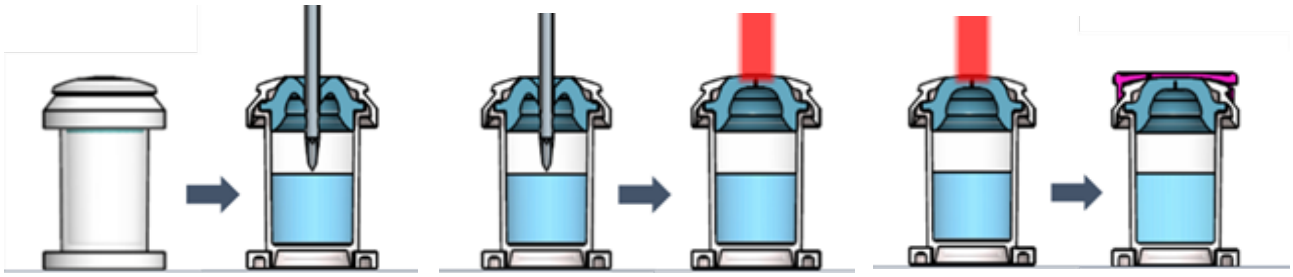
The AT-Closed Vial® is suitable for very small to large filling volumes. The vial is available in six formats ranging from 1 ml up to 50 ml.

AT-Closed Vial®	1 ml	2 ml	6 ml	10 ml	20 ml	50 ml
Height (in mm, +1 mm when 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

Enabling
Safe fill & finish operations

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

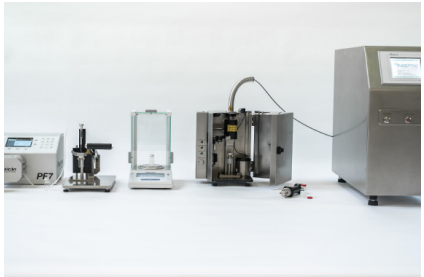
1. Filling: the vial is filled through the stopper with a specific sterile needle. After the piercing, the stopper mechanically recloses due to its elasticity.
2. Laser re-sealing: the stopper is resealed with a one second laser shot.
3. Capping: the sterile snap-fit cap is placed on the vial to protect the stopper until the collection of the product.



Filling Lines

To adapt to your specific needs, we have developed a complete range of Filling Lines. From manual to fully automated systems, our Filling Lines can be used at any stage of the product development process and through commercialization.

The Filling Lines are available in BSC/RABS, or SKAN isolators for increased safety.



Adapting
to your needs

Packaging

The AT-Closed Vial® is available in three packaging configurations in order to satisfy your specific needs:

- ⟶ AT-CryoBox™: 9 to 25 vials per package depending on the vial size
- ⟶ AT-Nest™: 25 to 88 vials
- ⟶ AT-Tray™: 91 to 377 vials

The AT-CryoBox™ is adapted to cryogenic storage .

Collection device

The AT-Adapt™ is a needleless collection device that has been developed to fit the AT-Closed Vial® (from 2ml to 50ml) and facilitate your process.

Our quality engagements

Validation Master Plan

A full Validation Master Plan and all tests are supplied with 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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