**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:
- **lean** (molded in ISO 5 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

**Cytotoxics**
- Radiopharmaceuticals
- Nanomedicines
- Unbreakable container, always closed to avoid contamination

**Cell therapy**
- Gene therapy
- Other low T° storage products
- Container Closure Integrity even in liquid nitrogen

**AT-Closed Vial®**

<table>
<thead>
<tr>
<th>Size</th>
<th>1 ml</th>
<th>2 ml</th>
<th>6 ml</th>
<th>10 ml</th>
<th>20 ml</th>
<th>50 ml</th>
</tr>
</thead>
<tbody>
<tr>
<td>Height (in mm, +1mm if capped)</td>
<td>33.10</td>
<td>33.10</td>
<td>39.30</td>
<td>49.80</td>
<td>61.20</td>
<td>84.90</td>
</tr>
<tr>
<td>External vial diameter (in mm)</td>
<td>18.30</td>
<td>22.30</td>
<td>25.00</td>
<td>25.00</td>
<td>30.00</td>
<td>36.00</td>
</tr>
<tr>
<td>Maximum volume filled (in ml)</td>
<td>1.35</td>
<td>2.25</td>
<td>7.60</td>
<td>11.70</td>
<td>21.80</td>
<td>52.10</td>
</tr>
</tbody>
</table>

**Cryogenic storage**
- can be cryopreserved while keeping Container Closure Integrity

**Colored caps**
- are available in different colors for product differentiation

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**Crystal® Filling Lines**

**PROCESS**

The overall filling process of the ready-to-fill AT-Closed Vials® 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® Filling Line.

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<table>
<thead>
<tr>
<th>Container</th>
<th>Crystal® M1 Filling Station</th>
<th>Crystal® L1 Robot Line</th>
<th>Crystal® SL1 Robot Line</th>
<th>Crystal® PX Filling Line</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max. output</td>
<td>180 u/h</td>
<td>600 u/h</td>
<td>600-700 u/h</td>
<td>6,000-10,800 u/h</td>
</tr>
<tr>
<td>Containment</td>
<td>AT-Closed Vial®</td>
<td>AT-Closed Vial®</td>
<td>AT-Closed Vial®, Prefilled Syringe, Open Glass Vial</td>
<td>AT-Closed Vial®</td>
</tr>
<tr>
<td>Containment</td>
<td>BSC or Isolator</td>
<td>RABS or Isolator</td>
<td>RABS or Isolator</td>
<td>RABS or Isolator</td>
</tr>
<tr>
<td>Typical footprint</td>
<td>1 m²</td>
<td>1.5 m²</td>
<td>1.5 m²</td>
<td>12-18 m²</td>
</tr>
<tr>
<td></td>
<td>11 ft²</td>
<td>16 ft²</td>
<td>16 ft²</td>
<td>130-195 ft²</td>
</tr>
<tr>
<td>Closing IPC</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Utilities</td>
<td>WFI: -</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Vacuum: -</td>
<td>-</td>
<td>Yes</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Electricity: Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

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.