

# **Restricted-access barrier systems**

Restricted Access Barrier Systems (RABS) are becoming increasingly popular within aseptic processing; the reason being that they offer effective product protection by providing a high level of separation between operators and the critical aseptic core. By using a combination of a physical barrier and dynamic airflow, the product protection that it can provide approaches that of an Isolator and makes it a viable alternative technology.

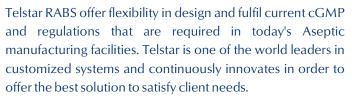
It should be noted however that RABS offer no means of containment for operator or environmental protection, should the product under manufacture be a toxic product or API (active pharmaceutical ingredient) carrying an OEL (Operator Exposure Limit) or a live viral product.

When the surrounding environment is ISO 6 and other procedural elements are in place RABS will provide ISO 5 environment in the critical zone. For operations which do not need to be performed in the sterile core (for example, over-sealing) a RABs will provide ISO 5 class laminar air flow with an ISO 7 background.

## RABS can either have Passive or Active ventilation:

- **Passive RABS**, Utilises the clean air from the cleanroom ceiling HEPA Filters and ventilation.
- Active RABS, Clean air is derived from on board HEPA filters and Fan(s) or via direct connection to a central air-handler.









### RABS can be either 'Open' or 'Closed':

- **Open RABS**, When the air has passed through the protected zone it spills into the cleanroom with no further filtration.
- **Closed RABS**, When the air has passed through the protected zone it is recirculated back to the supply HEPA filters or is filtered before it spills into the cleanroom.

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## Restricted-access barrier systems (RABS)

- •Simplicity in design with 304/316L stainless steel Frame •Fully opening vision panels in 10mm toughened safety glass
- or laminated glass •Glove port access in vision panels using HDPE elliptical glove ports offering the maximum possible operator arm movement
- •Uni-directional downward laminar flow over the whole area of the RABS at 0.45m/sec +/- 20% provided by either micro-perforated grill or polyester air distribution screen
- •EU Grade A (ISO5) conditions inside the barrier (with at least ISO 7 surrounding)
- •Active RABS use high efficiency EC fans (Green Tech)
- •Active RABS fitted with either grade H14 HEPA filters or U15 ULPA filters
- •Filter test ports
- •Pressure monitoring of filter differentials using 'magnehelic' pressure gauge
- •Automated air velocity control to compensate for filter burden
- •Can be furnished with specific manufacturers transfer ports
- •Can be furnished with environmental monitoring services entry points and utilities
- •Full qualification services (DQ,IQ,OQ)







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