

FOA - Steam air mixture sterilizer

Applications:

Bio-pharmaceutical

Food

Loads:



Processes:

Sterilization



Sterilization of aqueous solutions in sealed containers (such as LVPs – Large Volume Parenterals, vials, PFS – Pre-filled syringes, blister packs, etc.) share a common problem: the pressure inside the primary container is higher than the pressure of saturated steam outside at the same temperature. This can affect the product and/or the container itself.

FOA steam air mixture sterilizer is the most flexible and mild solution for the sterilization of LVPs and other heat sensitive products.

Our unique approach to counterpressure sterilization:

- **Flexibility:** control of critical process parameters designed to assure the highest flexibility of the sterilization cycle and to prevent any undesired deformation/damage of the containers, while providing the desired thermal treatment.
- **Total control:** temperature and total pressure control (air + steam). A flow deflector and one or more magnetic drives guarantee a uniform mixture spread.
- **Process optimization:** Load emerges dry and ready for the next process steps. Sterilizers can also be equipped with fully automatic un/loading conveyors for the highest productivity with virtually no maintenance inside the sterilization chamber. When the product is liable to separation or for accelerating thermal transition phases, the load can be rotated during the entire process.
- **Easy validation & integration:** Thema4 process controller is pre-validated according to GAMP5 and in compliance with CFR – part 21, thus resulting in shortest qualification time and minimizing project risks. Open system architecture that can be integrated with SCADA system and other Fedegari machines.
- **Highest productivity:** Fedegari R&D laboratory is available to develop the best treatment solution for your specific needs. We run tests with different loads and requirements.

Key benefits

No water consumption
(PW/UPW/WFI)

Load can be easily unloaded dry

No PVC blushing phenomenon

Powered by

Thema4

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Fields of application

FOA steam air mixture sterilizer is suitable for:

- Sterilization of parenteral solutions, liquids in sealed containers not deformable (eg. glass vials) and liquids in heat-sensitive sealed containers (eg. plastic bags or bottles)
- Terminal sterilization of pre-filled syringes (PFSs)

Design and technical features

- FOA steam air mixture sterilizer is equipped with AISI 316Ti stainless steel chamber
- Besides the standard versions (from 830l to 14.800l), loading capacity is fully customizable according to customer needs
- Chamber internal surface electropolished with a roughness $Ra < 0,4\mu m$
- One or two doors with vertical or hinged opening systems to cope with available space in the smartest possible way
- 5 probes PT100 RTD for temperature control (2 fixed – in the filter and discharge – and 3 flexible for the load)
- Automatic sterilization of the air filter with fixed temperature probe
- 2 ports for validation probes
- Fedegari exclusive patented door gaskets assure 100% tightness
- Piping and valves in stainless steel AISI 316L
- Patented magnetic drives remove any tightness problem deriving from seal wear, and minimizes maintenance, without requiring any lubrication

Special applications

Rotating load

The load is held in rotation thanks to a special rotating drum inside the chamber. The rotation drum has a magnetic coupling and is adjustable in speed, direction of rotation and intermittently. This system finds application in the treatment of suspensions and emulsions and ensures a better performance of the tightness tests for ampoules under vacuum and a more homogeneous heat transmission in the load.

