# STERIFILL

AMPOULE FILLING AND SEALING MACHINE



MASUFE

STERIFILL BIO

#### THE REGULATIONS ON THE PACKAGING OF PHARMACEUTICAL PRODUCTS ARE EVEN MORE STRINGENT DUE TO THE NEED FOR DRUGS AND MEDICINES TO WITHSTAND THE IMPACT OF EXTERNAL AIR AND GASES.

Ampoules are chosen for the packaging of various pharmaceutical, homeopathic and nutraceutical products when contact with glass only is required. Filled with a measured quantity of liquid, ampoules are considered ready-to-inject solutions with one more advantage: being 100% tamper proof.

The demand for ampoule filling machines is increasing because they offer cost-efficient and high capacity time-efficient filling. And this is where IMA Life expertise comes in. Considered as market leader in aseptic processing, IMA Life designed Sterifill a linear ampoule filling and sealing machine able to handle both opened (type B and C) and closed (type D) ampoules.

All design criteria needed in aseptic environments have been respected:

- Geometry facilitating the unidirectional air flow and cleanability.
- Reduced dimensions.
- High ergonomics.
- REDUCTION OF HUMAN INTERVENTION.



#### **MAIN FEATURES**

- NO AMPOULE NO FILL SYSTEM.
- Fully driven by brushless motors for high precision and gentle movements.
- POSITIVE TRANSPORT SYSTEM.
- EXCELLENT ACCESSIBILITY FOR DIRECT MAINTENANCE AND CLEANING.
- QUICK AND EASY TOOL-FREE SIZE CHANGEOVER.
- AVAILABLE AS A STAND-ALONE UNIT OR INTEGRATED IN COMPLETE PROCESSING LINES.
- SUITABLE FOR COMPLETE WALL INSTALLATION.
- CAN BE EQUIPPED WITH CIP/SIP SYSTEMS ALLOWING PROGRAMMABLE AUTOMATIC CYCLES WITH NO NEED TO REMOVE MACHINE COMPONENTS.
- Suitable for integration with LAF hoods system, RABS or isolator enclosures.
- Gas/oxygen safety valves, exhaust fume aspiration, reinforced PTFE hoses and special fastenings for gas/oxygen circuit available as standard.
- User-friendly HMI with Siemens touch screen. Option for PC based iFix HMI compliant with 21 CFR part 11 and GAMP standards.

### STERIFILL WORKFLOW



#### AMPOULE FEEDING AND TRANSPORT

Depending on the type of installation, ampoules can be loaded manually from trays or automatically from a depyrogenating tunnel. A conveyor belt guides the ampoules to a starwheel transferring them to the infeed scroll establishing appropriate spacing. An intermediate starwheel, built with three movable sectors for continuous or alternate feeding, guides the ampoules to the comb transport system which holds them gently from the body while transferring the ampoules through the filling and sealing stations.

#### **FILLING UNIT**

The dosing station mounts stainless steel or ceramic volumetric rotary piston pumps. Peristaltic pumps are also available as an option.

A centring device allows precise introduction of the needles into the ampoule during filling and/or nitrogen purging. The filling volume can be set by the HMI and is adjusted by a servomotor. The dosing unit is equipped with a suck back system to prevent the product dropping on the ampoule neck causing glass bubbles, black spots and product carbonization.





#### **SEALING UNIT**

The sealing unit mounts independent pre-heating and final sealing stations featuring two different burning temperatures, adjustable control of gas and oxygen flows according to the ampoule glass thickness and production speed.

The flames are activated electronically, the ampoules rotate (adjustable speed) during the entire closing process and are closed by fusing the glass while gentle grippers remove the trims allowing for perfect forming of the glass pearl or lens on the ampoule top and rejecting the trims in a bin. The gripper driving mechanism is fully closed to avoid exposure to the flames. A gas shut-off system is automatically activated in case the flames go out.



### STERIFILL WORKFLOW





#### **STATISTICAL IPC**

Upon request, Sterifill can be fitted with an In-Process Control system for statistical weight check.

Once the containers are conveyed under the filling station, the lateral guide is lowered and the empty containers are automatically transferred by vacuum onto the load cells for tare detection. After dosing the containers are moved again onto the load cells to detect the gross weight.

Statistical vial weighing can be regularly set or manually managed by the HMI.

100% weight control available to weigh ampoules at the beginning of the process or, if required, at any time.



#### AMPOULE OUTFEED AND UNLOADING

After the sealing phase, the ampoules are automatically discharged onto an outfeed tray which can be positioned in line or at 90° depending on the customer's requirement. As an option, the exit can be positioned in the rear side of the machine outside the filling area or in line. Connection with an inspection machine, external ampoule washer, coding machine or labeller is also possible.



### **STERIFILL COMBI**





FEATURING THE SAME DESIGN CONSTRUCTION AND TECHNICAL CHARACTERISTICS, STERIFILL IS ALSO AVAILABLE IN THE COMBI VERSION TO PROCESS AMPOULES AND VIALS ALTERNATELY WITH A QUICK AND EASY CHANGEOVER.



When processing vials the pre-heating and sealing stations are by-passed and vials are directly conveyed to the stoppering unit, which is supplied as an option to be integrated in the machine.

The unit consists of a vibratory bowl to feed the stoppers, a stoppering head which keeps the stoppers in position by vacuum and an elevating system to lift the vials under the stoppering carousel to complete the closing phase. This system is suitable for both liquid and lyophilization stoppers.

After stoppering, the vials are conveyed onto an outfeed belt which transfers them to the downstream machine (i.e. capping or freeze dryer). A rejection unit collects the vials automatically rejected in case of a missing stopper or incorrect placement.





## TECHNICAL DATA

STERIFILL

STERIFILL COMBI



	STERIFILL B4	STERIFILL B4 COMBI	STERIFILL B6	STERIFILL B6 COMBI	STERIFILL B8	STERIFILL B8 COMBI	STERIFILL B10	STERIFILL B10 COMBI
Output - ampoules (pieces/minute)	200		300		400		500	
Output - vials (pieces/minute)	-	150	-	225	-	300	-	375
Filling pumps	4		6		8		10	
Filling range (ml)	0.5 - 20	0.5 - 50	0.5 - 20	0.5 - 50	0.5 - 20	0.5 - 50	0.5 - 20	0.5 - 50
Ampoule diameter (mm)	10.75 - 2.5							
Vial diameter (mm)	-	16 - 42.5	-	16 - 42.5	-	16 - 42.5	-	16 - 42.5
Standard voltage	400 V - 50 Hz							
Installed power (kW)	18	20	18	20	18	20	18	20
Weight (kg)	1800	2000	1900	2100	2000	2200	2100	2300
Machine dimensions (mm)	A - 3300 B - 1150 C - 2020	A - 3600 B - 1700 C - 2020	A - 3300 B - 1150 C - 2020	A - 3600 B - 1700 C - 2020	A - 3300 B - 1150 C - 2020	A - 3600 B - 1700 C - 2020	A - 3650 B - 1150 C - 2020	A - 3950 B - 1700 C - 2020

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