# FILL-FINISH SOLUTIONS

FOR FLEXIBLE AND MULTI-PRODUCT MANUFACTURING

IMA LIFE

Aseptic Processing & Freeze Drying Solutions

# Table of contents



IMA LIFE

Aseptic Processing & Freeze Drying Solutions

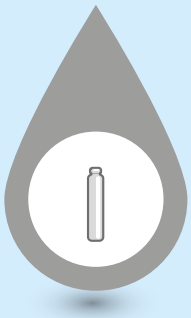
# **STERILE FILL-FINISH OPERATIONS** FOR READY-TO-USE

CENTRAL GOAL IS TO ACHIEVE FLEXIBLE PRODUCTION IN A SAFE, ASEPTIC ENVIRONMENT, IMPLEMENTING COST-SAVING SOLUTIONS TO REDUCE TIME-TO-MARKET.

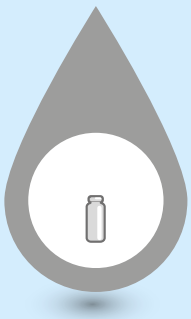
## MEETING THE CHANGING DEMANDS FOR PARENTERAL PRODUCTS

The pharmaceutical industry has been progressively embracing injectables as a consistently profitable business sector. The recent industry shift to biologics and biosimilars has further contributed to establishing a growing market for injectables and supporting technologies, leaving injection as the only practical route for the delivery of macromolecules and biologics in particular.
For decades, injection has been largely limited to in-patient use.
The introduction of **prefilled syringes and injection devices** has reduced the fear factor associated with outpatient injections and also minimised the likelihood of errors in preparing and administering a subcutaneous injection.
With the development of new parenteral products and specialised therapies for small patient populations and the increasing trend for user-friendly and safer self-administration systems, pre-filled syringes and Ready-To-Use (RTU) components, are becoming the preferred solution among the different parenteral dosage forms.

Therefore, pre-filled syringe and cartridge-based injectables have evolved into a manageable dosing strategy for a variety of medical conditions.
The steady growth of these next-generation, targeted therapies for parenteral delivery and relevant dosing forms have both helped increase the demand for aseptic fill-finish operations. As fill-finish processes represent the last step prior to product packaging, all operations are critical and failures in the integrity of the fill-finish stage can cause potential risks regarding contamination or drug degradation.
For these reasons, the pharmaceutical industry requires increased implementation of specialised capabilities and of emerging robotic technologies to create a new set of sterilisation, handling and filling challenges, so as to **improve product quality and manufacturing efficiency**.

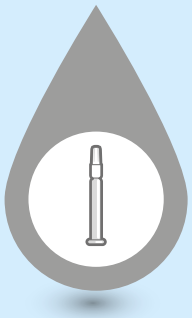


Cartridge size
**1 ml - 20 ml**

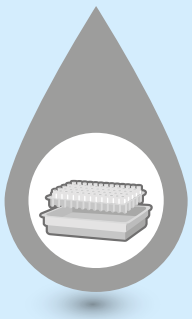


Vial size
**2 ml - 50 ml**

# COMPONENTS



Syringe size
**0.5 ml - 50 ml**



Nest and Tub size
**up to 160 pcs**

Meeting the growing demand for multi-product, fill-finish operations, IMA Life has designed and implemented a flexible and reliable machine portfolio for the filling and closing of a wide range of ready-to-use disposable components.

- INJECTA, the ultimate, innovative, fully robotic fill-finish machine for RTU components pre-arranged in nest & tub or trays.
- Steri Lif3, fully automatic aseptic filling, stoppering and capping machine using robotics for handling RTU components pre-arranged in nest & tub.
- Sterifill RS Series, automatic filling and stoppering machine for handling RTU components pre-arranged in nest & tub.

# SOLUTIONS FOR THE HANDLING OF PRE-STERILISED

Tub debagging & relevant transfer to the isolated area

Liner and lid disposal

## FULLY AUTOMATIC OPENING OF STERILE PRIMARY PACKAGES: A HIGH DEGREE OF AUTOMATION

At IMA Life, the fully automatic opening of sterile RTU packages is performed by specially designed six-axis robots, which take care of all the critical aseptic operations.

The primary packaging feeding area is usually surrounded by a cRABS area, separating the nearby isolated processing area.

After a pincer device performs pick-up, the overwrapped tub is automatically transferred to the cutting station, where the overbag is opened by a robotic cutting arm.

In case the primary package is supplied in a double-bag configuration (inner + outer bag solution), a double-cutting station is installed. The cut is made by keeping the bag flaps in a closed and fixed position. After cutting, the package is instantly transferred by an internal transfer port to the isolated, processing area. To preserve the sterility of the tub, the bag flaps are opened by the suction cups, only once the tub is physically transferred to the isolated area. If required, after unwrapping, the tub can be moved to the decontamination unit. The whole tub-opening unit is **completely robotized** and no operator intervention is required.

A robotic de-lidding station removes the Tyvek™ covering sheet from the top of the tub and disposes of it.

The internal liner is then automatically removed from the opened tub, and disposed of. The tub top perimeter edge can be pre-heated by a dedicated warming station, on request.

# PRIMARY PACKAGING

Automatic bag-cutting

Inner bag manual cutting under laminar airflow hood

## SEMI-AUTOMATIC OPENING OF STERILE PRIMARY PACKAGES: A PERFECT MATCH BETWEEN AUTOMATION AND HUMAN INTERVENTION

As an alternative, handling of primary packaging can be performed semi-automatically or in part manually.
In the first case, with the semi-automatic procedure, the operator places the sealed package on the cutting station. The overbag is then automatically cut and the tub is automatically transferred to the following station. The overbag is removed manually and disposed of by the operator. Using gloves, the operator removes the Tyvek™ lid and liner and disposes of all the scraps.
In the second case, again using gloves, the operator places the sealed package onto the cutting station.
After positioning the overwrapped tub on the cutting station, using gloves, the operator performs cutting manually and subsequently pushes the tub gently onto a sloped chute towards the separate processing area, taking care of overbag removal and disposal. Furthermore, still with gloves, the operator removes the Tyvek™ lid and liner and disposes of all the scraps.
In both cases, the surrounding area is normally confined beneath Restricted Barrier Systems or under a laminar airflow hood, providing a better degree of product quality assurance.

Outer bag manual cutting under Laminar airflow hood

Manual de-lidding and linear removal under isolator

# **INJECTA.** THE FUTURE OF ASEPTIC PROCESSING

INJECTA MEETS THE CURRENT NEED TO DELIVER A VARIED PRODUCT PORTFOLIO IN TERMS OF PRIMARY PACKAGING MATERIALS (SUCH AS VIALS, CARTRIDGES AND SYRINGES FOR PARENTERAL USE) AS EXPECTED BY THE LATEST MARKET REQUIREMENTS.

## INJECTA'S FULLY ISOLATED ROBOTIC TECHNOLOGY DISRUPTS THE CONVENTIONAL APPROACH TO ASEPTIC PROCESSING

In aseptic processing, operators are the primary source of contamination. Although human operators represent a potential risk in sterile areas, pharma manufacturing remains predominantly human.

Therefore, one of the focal topics for pharmaceutical manufacturing today is how to improve the use of robotic automation in a toward-gloveless, isolated environment. The ideal outcome is the creation of a digitally controlled aseptic process with little to no human intervention.

To achieve maximum possible improvement in safety and productivity, **INJECTA's full fill/finish process is completely based on robotics operating in a closed, isolator environment**.

Whereas conventional attempts to use robots are typically confined to just one step of production, i.e. simply for moving vials from station to station or for removing the cover from a tub of nested containers, INJECTA uses the **full potential of its robots**.

INJECTA is designed as a whole, exploiting all robotic capabilities in an integrated system. Kawasaki's seven-axis robot arms are designed for the lowest particle shedding.

They are resistant to positive/negative and high pressures and fully compatible for decontamination using $H_2O_2$ vapour.

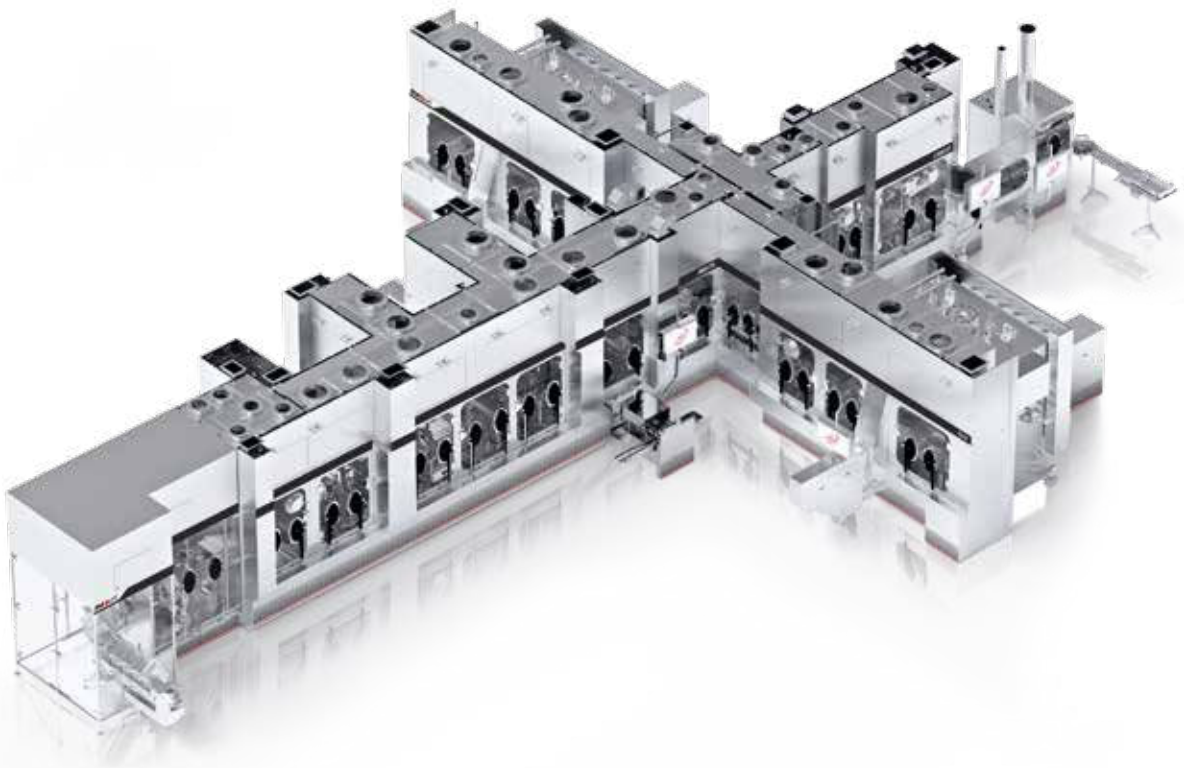
INJECTA's specialised robots not only provide precise, consistent handling activities, but also offer a high level of flexibility: they are completely digitally controlled with Industry 4.0 capability. No human intervention is required: all activities/issues are solved through robot interactions.

INJECTA inbuilt "combi" configuration guarantees a complete, contained integrated production system with no use of interchangeable production modules to adjust production processes. INJECTA is flexible and precise in terms of quality. It works with multiple primary packaging components. Its design is intrinsically modular and meets multiple requirements from small-scale clinical trial batches up to medium-high production levels.

Single-use materials such as Ready-To-Use primary containers, disposable inner/outer bags, etc. are disposed of within the system. Its advanced design allows faster setup and efficient product changeover, involving therefore a **faster VPHP cycle development with respect to conventional isolated lines**.

Results are reduced filling line downtime, increased capacity and greater flexibility.

INJECTA TRACES THE ROADMAP FOR A REAL AND COMPLETE FILL-FINISH PROCESS MODERNIZATION.



# INJECTA

By embracing and adopting new robotic technologies throughout all production operations, from outer/inner bag opening to the stoppering station, INJECTA allows for a very smooth production process, drastically reducing human interventions and therefore cross-contamination risks.

Advanced robotic handling

INJECTA'S GROUND-BREAKING INNOVATION IS THE 100% IPC OF ALL PROCESSED PRODUCTS, WITH SINGLE REJECTION OF INDIVIDUAL NON-CONFORMITIES, WHILE ENSURING HIGH MACHINE PERFORMANCE.

## THE STRATEGY OF FLEXIBILITY

Benefits at a glance of INJECTA's fully isolated robotic fill-finish operations:

- **High flexibility** for multi-product and multi-format handling enabling rapid switches between different primary packaging for drugs and other products.
- **High versatility**: the RTU containers can be accurately and efficiently filled and closed in a nest or by de-nesting operations. The robotised individual component handling solution (i.e. de-nesting configuration) is ideal for high-level quality control requirements and high-potent drug filling.
- **Improved protection** of the fill-finish process and cross-contamination risk reduction with gloveless barrier isolation systems.
- **Perfect integration** with IMA isolator with reduced shell width and positive impact on space ergonomics.
- **Asynchronous robotic movements**, allowing single operation completion
- **All-in-one**, unique and integrated fill-finish solution: in-line lyophilisation process and capping operations for vial handling.
- **Available configuration** with vial feeding from depyrogenation tunnel.
- **Compliance with Industry 4.0** requirements for interconnected production data: data accessibility, circulation and exchange by integrated automation platform.

Filling & 100% check-weighing

Vial stoppering with lyo stopper

## ASEPTIC FILLING AND 100% IN-PROCESS CONTROL

If flexibility is crucial for high-value and medium-low production batches, INJECTA is naturally flexible. It can easily combine and perform robotized fill-finish operations both in-nest and in de-nesting configurations.

As a de-nesting solution, INJECTA's flexible handling units allow for precise removal of the components from the nest. As a result, individual components are filled, check- weighed, stoppered and then replaced into the nest, in the case of syringes and cartridges (the renesting operation can be performed inside or outside the isolator), or transferred by a conveyor belt to complete the process.

In both solutions, an in-line nozzle carrier performs filling with a bottom-up movement. All adjustments (speed, height and stroke) are directly set via the HMI and all data are consequently stored inside the recipe.

The number of loading cells used to perform 100% check-weighing depends on the number of filling nozzles fitted to the machine. INJECTA can be configured for 1 or 2 filling groups for clinical trials of small production batches and for 6 or 10 filling groups for high production demands. INJECTA can be equipped with peristaltic or volumetric filling pumps (driven by the same system) or with a time/pressure dosing system, performing up to 36,000 pcs/hour (referred to 1ml syringe).

The use of peristaltic pumps is becoming more common in the aseptic environment as they are fitted for handling recently developed biotech drugs.

## STOPPERING AND REJECTION

The stoppering process is performed as follows:

- On **INJECTA 6**: by a linear stopper feeding system with stopper/plunger up to 20 mm. Unlike conventional systems, this innovative group is made of small-sized components.
  It is the ideal solution for RTP transfer ports, in compliance with Annex 1 requirements in terms of the sterilisation process.
- On **INJECTA 10 and INJECTA 36**: by a vibrating bowl.

All adjustments regarding speed, height and stroke can be carried out via the HMI. All data are stored in the recipe.

In the case of individual, non-conforming products, INJECTA 6 and INJECTA 10 perform an automatic single rejection of non-conformities after stoppering.

**INJECTA 36** can be equipped with a plunger presence check to allow the manual rejection of non- conformities.

Pick up of filled RTU vials

## INTEGRATED (VIAL) CAPPING UNIT AND DOWNSTREAM CONNECTIONS WITH FREEZE DRYERS

**INJECTA 6** and **INJECTA 10** can be integrated with an in-line lyophilisation process, where an automated loading/unloading system handles products into and out of the freeze dryer.
**INJECTA 36** is principally dedicated to the production of syringes and cartridges in a nest.
When all filled and closed RTU containers are finally processed, the following operations are performed automatically:

- **in the case of syringes and cartridges which are filled in a nest**, the nest is re-inserted inside the tub and then transferred to the next step.
- **in the case of syringes and cartridges which are filled by denesting**, the container is renested inside or outside the isolator and reinserted into the tub.
- **in the case of lyo vials**, a dedicated conveyor moves the pre-stoppered vials to a downstream automatic loading/unloading system and relevant freeze dryer.
- **in the case of liquid vials or vials coming from the freeze dryer**, the capping operation is carried out by a separate alu-capper. The capped vials are transferred to a dedicated vial collection system and then moved to the next step. The empty nest and tub will exit the machine via a separate outfeed.

Robot overview

Single reject from the nest

## INJECTA 36. INCREASING YOUR POTENTIAL

**INJECTA 36** was designed in an aim to boost machine's potential by combining high-robotic technology with high-speed production of Ready-To-Use syringes and cartridges.
Taking advantage of the acquired knowledge of robot capabilities, INJECTA 36 introduces an innovative solution for 100% In-Process-Control and check-weighing, which is particularly suited to the vaccine market.
We have developed the machine in such a way as to handle RTU vials using a dedicated de-nesting unit placed outside the machine.
INJECTA 36 ensures statistical weight control up to 36,000 pcs/hr or 100% weight control reaching 6,500 pcs/hr.
INJECTA 36 performs automatic, robotic weight cell calibration.
In the case of CIP SIP, the machine is equipped with automatic insertion of filling nozzles.

## INJECTA KEY FEATURES

- Full integration with robotic or semi-automatic upstream primary package handling
- Easy access to filling and stoppering areas
- Set for 1-2 filling groups for clinical trial batches or 6 - 10 filling groups for high production demands
- Operating units (filling, IPC & stoppering) situated in a remote location away from the product path
- Revolutionary 100% in-line process control, with single rejection of individual non-conformities. Availbale on INJECTA 6 and INJECTA 10, only.
- Robotic control of the weighing cells based on calibrated weight already positioned inside the isolator, only on INJECTA 36.
- Use of a linear stopper feeding system, reducing particle generation from vibratory bowls, only on INJECTA 6.
- Empty tub/tray transfer performed at robot base level without the use of conveyors, inside or outside the isolator.
- CIP/SIP system available on request: all product contact parts are cleaned and sterilised without removing them from the machine.

# **STERI LIF3.** READY TO FILL

STERI LIF3 is a low speed fully automatic aseptic filling, stoppering and (vial) capping machine for the processing of ready-to-use syringes, vials & cartridges in tub.

Combining essential features with an innovative robotic technology, it efficiently responds to the increasing market demand for a highly variable production process. If current market trends in aseptic fill- finish are requiring more and more agile manufacturing strategies, STERI LIF3 allows the adoption of unique fill-finish equipment for different container formats with easy and fast change of the packaging/format (syringes, vials & cartridges).

Flexible and multi-product fill-finish operations are becoming more crucial due to changes in the pharmaceutical industry where most of the new injectables require a delivery model that is patient-centric, safe and cost effective. That happens best with a closed robotic filling system which reduces the sources of contamination risk and consequently maintains the sterility of the equipment and of the finished drug product.

Inspired by the advancements in robotics, STERI LIF3 provides an automated, filling and closing process overcoming the traditional aseptic model and relevant handling mechanisms. As a result, it can offer faster and gentler processing of different products, giving the flexibility to easily change the process or the type of container being filled, with no operator intervention. As a result, reducing the operation steps and advancing production control, STERI LIF3 improves production efficiency.

STERI LIF3 has been specifically conceived to provide for the highest aseptic assurance. It can easily work under isolation technology or, depending on the application requirements, be integrated in a Restricted Access Barrier System (RABS) or even under a conventional room with a laminar airflow hood. Being completely isolated from the outside, there is no human intervention, no glass- to-glass contact, no product conveyors or rotary tables that can generate any potential risks to the product.

It is for all these reasons that STERI LIF3 is the ideal solution to meet the current market need for small batch flexibility.

STERI LIF3 robotic system can offer the necessary flexibility, ease of use and sterility assurance required to process high-value drugs into multiple formats.


STERI LIF3 ROBOTIC ARMS OFFER REPEATABILITY WITH THE FLEXIBILITY TO EASILY CHANGE THE PROCESS OR THE TYPE OF CONTAINER BEING FILLED.

Fully automatic nest pick-up arm

Filling station

## BENEFITS AT A GLANCE OF STERI LIF3'S ROBOTIC FILL-FINISH OPERATIONS:

- **Increased flexibility**: unique fill-finish equipment for different containers
- **Easy and fast change** of the package/format with minimal/no size changeover
- **Increased quality**: absence of glass-to-glass contact during operations
- **Reduction of operator intervention**: minimisation of cross contamination risks
- **Easier and more effective maintenance** and cleaning
- **Fewer operation steps and advanced operational control**: less exposure time of the drug to the aseptic environment and product handling optimisation
- **Integrated capping unit**, in segregated area, or in the case of freeze dryer and automatic vial loading/unloading, in-line connection to a downstream capping machine

# STERI LIF3

100% In-Process Control

## FILLING OPERATIONS AND IN-PROCESS CONTROL

The Ready-To-Use components are provided pre-sterilised and configured in nests inside tubs. Standard-sized nest & tub configurations allow for the greatest stability and product safety: all containers are securely fixed during handling and transportation.

Once the nest is picked up from the tub and loaded on the nest-holding support by the robotic arm, two single RTU components are de-nested and transferred to the filling area. The two components are placed onto two loading cells for tare check-weighing, filling and gross check-weighing sequences.

STERI LIF3 is set for 2 filling groups ensuring a production speed of up to 1,200 pcs/hr. Multiple dosing options are available such as volumetric or peristaltic pumps. The pumps are fitted in line and accessible from machine operator side. The single-use filling systems (i.e. peristaltic pumps) are preferred in presence of a time-intensive CIP/ SIP process, which is available on demand.

The dosing needles are provided with a self-centring, adjustable device and servo-driven, vertical movement for bottom-up dosage. The micrometric dosage volume adjustment is servomotor-driven and controlled via the HMI. All values are stored inside the product recipes.

The IPC system controls the automatic self-adjustment of the dosing, within the pre-set tolerance limits.

Stoppering of RTU vials

## STOPPERING

After In-Process Control is accomplished, the two single RTU components are picked up and moved to the stoppering station.
STERI LIF3 is provided with a standard "venting type" stoppering station complete with an AISI 316L vibrating bowl and a dedicated linear chute for stopper orientation and insertion into each component.
Stoppering is performed by a dedicated tube and pin insertion. As optional, vacuum stoppering for RTU syringes can be installed.
An automatic discharge system, discharges the single non-conformities due to incorrect weight or missing stopper onto a dedicated holder system.

# STERI LIF3

Working area overview

## INTEGRATED VIAL CAPPING UNIT OR CONNECTION WITH DOWNSTREAM CAPPING UNIT

In the case of vial processing, capping can be integrated or carried out by a downstream capping machine. In both cases the capping check is performed by the PLC of the filling unit.
The two stoppered RTU components are automatically transferred towards the capping station.
The capping pick-up and placement onto the RTU vials is carried out by the robotic arm.
During capping operations, the vials rotate against the idle roller to minimise particle generation. All operations are servo-driven and automatically adjusted via the HMI.
The adjustment control of the capping force is available as an optional feature.

## DOWNSTREAM CONNECTIONS

When all filled and closed RTU containers are finally processed, the following operations are automatically performed:

- **in the case of RTU syringes or cartridges**, the filled nest is re-inserted into the tub and then moved out of the STERI LIF3.
- **in the case of RTU vials**, the two stoppered components are automatically transferred towards the integrated capping station. The capped vials are finally collected on a dedicated vial-collection system and then moved to the next secondary packaging steps.
  The empty nest and tub are moved out of the machine by a separate outfeed.
- **in the case of RTU lyo vials**, a dedicated device moves the pre-stoppered components to a downstream automatic loading/unloading system and relevant freeze dryer. Capping operations are subsequently carried out by a separate capping station.
  The capped vials are finally collected on a dedicated vial-collection system and then moved to the next secondary packaging steps. The empty nest and tub are moved out of the machine by a separate outfeed.

Capping of RTU vials

## STERI LIF3 KEY FEATURES

- Easy upgrade with fully robotic or semi-automatic upstream primary package handling
- Extremely precise filling operations for high product yield
- Possible filling of two different products inside the same vial
- 100% and statistical IPC
- Separate, downstream capping station or integrated capping area, segregated from filling and stoppering area to avoid cross-contamination
- Completely brushless driven
- Ideal for exposure to VPHP sanitisation
- Compact design
- Connection to automatic vial loading/unloading system and freeze dryer

# **STERIFILL RS SERIES.** SIMPLIFYING FILL-FINISH DESIGN

SIMPLIFYING ITS FILL-FINISH DESIGN, STERIFILL RS SERIES ENSURES AN EASY AND AGILE HANDLING OF NESTED GLASS COMPONENTS, PRESERVING STERILITY REQUIREMENTS.

Amongst the several parenteral dosage forms available on the market for the development of a new drug product, pre-sterilised syringes are on the rise and have become a preferred format.
The ongoing biopharmaceutical boom has contributed to promote the growth of the pre-filled syringe market. Actually, pre-filled syringes can address the numerous issues linked to biologic drugs as they are easy to use, ensure a high dosing accuracy and contribute to minimising product loss, which is another major advantage when it comes to expensive biopharmaceuticals.
Companies targeting biologics and biosimilars face a new frontier in development and manufacturing, as these drugs are complex, diverse, and difficult to produce.
This complexity is promoting the adoption of modern methods and more flexible technologies to improve production quality and manufacturing efficiency.
In order to address patient safety and dosing accuracy, as main issues for injectable administration, IMA Life offers a highly flexible and reliable solution to meet this market demand with its STERIFILL RS Series.
The STERIFILL RS Series has been specifically designed for the filling and stoppering of nested, pre-filled syringes. It is also suited to handling all other pre-sterilised Ready-To-Use container formats, such as vials and cartridges, for medium to small production batch sizes.
The STERIFILL RS series allows for flexible methods of production for injectable pharmaceuticals, providing the necessary agility and ability to allow faster filling operations with minimal changeover time.


Sterifill RS Series under an isolation system

Sterifill RS Series automatic denesting at infeed

The broader shift in the pharmaceutical market from blockbuster drugs to specialised, targeted therapies intended for small patient populations is creating a need for fill-finish operations with flexible capabilities. Actually, a multi-product, small-batch aseptic filling machine must be flexible to constantly keep up with the changing demands for new drug-delivery systems and/or packaging types (e.g. vials, cartridges, pre-filled syringes), offering at the same time a cost-saving solution as well as reduced lead times for installation.
Meeting the changing demands for sterile fill-finish operations, the STERIFILL RS Series allows for:

- **increased automation in fill-finish operations**, reducing many of the potential sources of contamination risk
- **implementation of single-use technologies**, such as peristaltic pumps, which is cost-saving (no need to clean and validate the components that come into contact with the product) and also a time-saving solution (no need for intensive CIP/SIP processes), both improving machine availability and reducing production time
- **fully automatic 100% in-process control**, which definitively improves the quality of the filling process
- **easy integration** with different containment solutions.

The diverse considerations related to sterile fill-finish manufacturing such as the safeguard of equipment sterility, protection against contamination of the container and of the drug product itself, make it especially critical to install a proper containment solution. The STERIFILL RS Series has been specifically conceived according to cGMP and FDA regulations to work under isolation technology or Restricted Access Barrier System (RABS) or even under conventional rooms with a laminar airflow hood.
In a nutshell, the STERIFILL RS Series offers the highest possible flexibility in a very compact space, handling different primary packaging types and combining semi-automatic or fully automated processes. The primary package infeed can be either manual or semi-automatic, so as to accommodate a variety of packaging formats. Hence filling is fully automated.

## ISOLATORS ARE BECOMING INCREASINGLY COMMON AS THEY CONSISTENTLY SEPARATE THE ASEPTIC AREA FROM ITS SURROUNDINGS

# STERIFILL RS SERIES

In case of viscous products or in the presence of air bubbling during dosing due to product features, a special vacuum filling system can be integrated. Before filling, the air is vacuum-sucked to allow the product to reach the bottom of the container, avoiding air bubbling. All product contact parts are made out of AISI 316 L. STERIFILL RS is fully equipped with servomotors to drive all machine mechanisms in order to achieve maximum flexibility in handling and in filling accuracy.

RTU cartridge filling and plugging

## BENEFITS AT A GLANCE OF THE STERIFILL RS SERIES AUTOMATIC FILL-FINISH OPERATIONS:

- TRADITIONAL FILLING CONCEPT COMBINED WITH THE HIGHEST FLEXIBILITY: UNIQUE FILL-FINISH EQUIPMENT FOR DIFFERENT CONTAINERS
- EASY AND FAST CHANGE OF THE PACKAGE/FORMAT WITH MINIMAL/ NO SIZE CHANGEOVER
- HIGH DEGREE OF AUTOMATION: MINIMUM OPERATOR INTERVENTION AND REDUCTION OF CROSS-CONTAMINATION RISKS
- HIGH STABILITY AND SAFEGUARD OF THE RTU COMPONENTS: ALL CONTAINERS ARE SECURELY FIXED AND KEPT INSIDE THE NEST DURING THE ENTIRE PROCESS
- COMPACT, ERGONOMIC AND SIMPLE DESIGN: EASY ACCESS, MAINTENANCE AND CLEANING.

Filling and pre-stoppering
of RTU vials with lyo products

100% In-Process-Control of RTU vials

## FILLING: ALL STEPS IN A HIGHLY AUTOMATED PROCESS

The Ready-To-Fill, pre-sterilised syringes or other components are supplied and handled in nests, placed inside tubs, holding up to 120 vials/160 syringes or cartridges each.
The operator will manually remove the outer bags, the lid and the liner over the tubs, and then take the syringe nest and place it on a central plateau placed outside the machine working area.
As an option, the machine can be equipped with automatic extraction and positioning of the nest on the plateau and with the automatic re-insertion station to place the nest back in the tub. This solution ensures easy handling of glass components, preserving sterility requirements.
Once the nests are positioned under the filling station, filling is performed at 2 or 5 units at a time ensuring a production speed up to 4,800 pcs/hour with 2 filling pumps. The dosing station is equipped with 2 or 5 filling groups, i.e. rotary piston pumps either in ceramics, driven by servomotor or other single-use filling systems, typical of aseptic operations such as peristaltic pumps. The filling volume is automatically defined by the machine, according to the recipe and the sizes stored in the HMI.
The filling needles enter the RTU component without any contact with the container. Nitrogen gas purging can be implemented during the filling and stoppering operations, on demand.

# STERIFILL RS SERIES

IN-PROCESS CONTROLS ARE AN IMPORTANT FACTOR IN FURTHER IMPROVING THE QUALITY OF THE FILLING PROCESS.

100% or Statistical IPC: weighing cells detail

## FULLY AUTOMATED 100% AND STATISTICAL CHECK-WEIGHING SYSTEM

In the case of 100% or statistical in-process control, two or five empty RTU components (depending on the numbers of dosing units) are automatically extracted from the nest by a pushing device. Then a mechanical arm, driven by servomotors, places them onto the individual two or five weighing cells for tare check-weighing. After filling, the RTU components are extracted again and replaced on the weighing cells for gross check-weighing completion.
Electronically controlled scales calculate the effective net weight of each single component, by difference between tare and gross weight.
The IPC system controls the automatic self-adjustment of the dosing, within the pre-set tolerance limits.

## STERIFILL RS SERIES KEY FEATURES

- Set for 2 or 5 filling groups
- Peristaltic or volumetric pumps for dosing accuracy
- Fully automated 100% or statistical in-line process control
- Vacuum filling system to avoid air bubbling, for specific-viscous products
- High flexibility to fill and close nested components with fast changeover times
- Simple and agile solution for small-scale manufacturing
- Easy upgrade with a fully robotic or semi-automatic upstream primary package handling
- CIP/SIP system available on request: all product contact parts are cleaned and sterilised without removing them from the machine.

Plugging of RTU syringes

Stoppering detail

## STOPPERING STATION

The stoppers are fed by means of a vibratory bowl and a linear chute: a pick & place arm picks the stoppers up (2 or 5 at a time) transferring them in position, over the components. The stoppers are then internally inserted to a depth which is automatically defined by the machine, according to the recipe and the sizes stored in the HMI. All stopper contact parts are made of AISI 316. Like the filling process, the stoppering operation is performed, while all RTU components are safely arranged and kept inside the nest. Even during stoppering, in the event of air bubbling, the stoppering operation is performed after air extraction by vacuum suction.

When all filled and closed RTU containers are finally processed and automatically re-arranged inside the nest, the following operations are automatically performed:

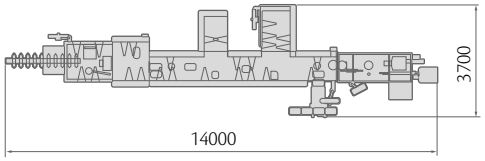
- **in the case of RTU syringes, cartridges or non-lyo vials**, the filled nest is re-inserted inside the tub and then moved to the secondary packaging step.
- **in the case of lyo vials**, a dedicated device moves the pre-stoppered lyo vials to a downstream automatic loading/unloading system and relevant freeze dryer. Capping operations are subsequently carried out by a separate capping station. The capped vials are finally collected onto a dedicated vial-collection system and then moved to the secondary packaging step. The empty nest and tub will exit the machine via a separate outfeed.

# TECHNICAL DATA

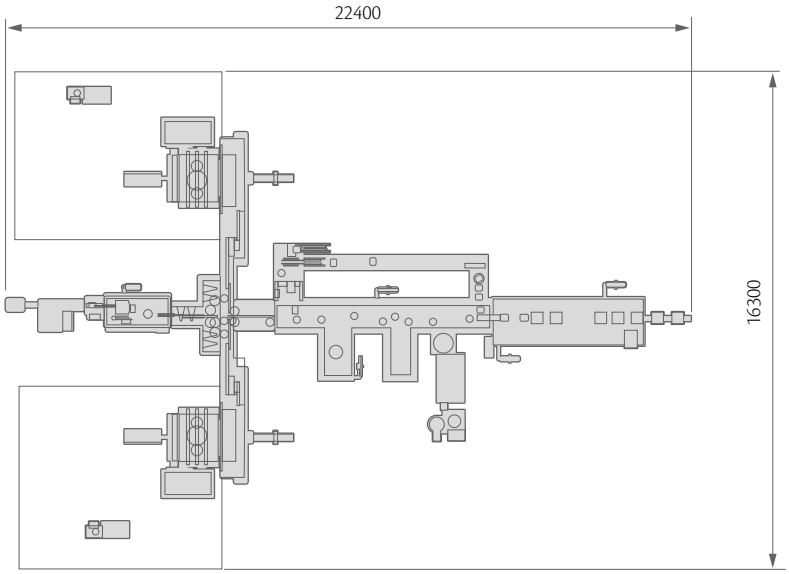
## INJECTA
## OPTIONAL UNITS

- Available dosing systems:
  - Volumetric pumps
  - Peristaltic pumps
  - Time/Pressure
- Nitrogen purging:
  - During filling
  - During stoppering
- IPC 100% or statistical
- Vacuum filling, only on INJECTA 36
- Vacuum stoppering
- CIP/SIP system with automatic insertion of dosing nozzles, only on INJECTA 36

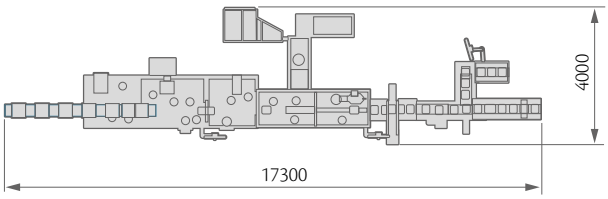
INJECTA 6




INJECTA 10




INJECTA 36

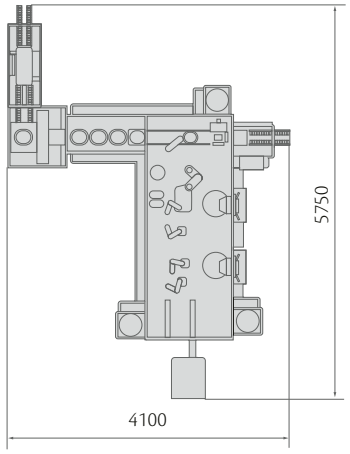



| | INJECTA 6 | INJECTA 10 | INJECTA 36 |
|---|---|---|---|
| Automation | Fully robotic automated | Fully robotic automated | Fully robotic automated |
| Footprint | 6.100 x 3.600 x 2.080 [L x W x H] | 7.200 x 4.500 x 2.080 [L x W x H] | 3.400 x 2.050 x 2080 [L x W x H] |
| IPC | 100% at full speed | 100% at full speed | 100% |
| Format range vials | Ø 16 - 42.4 mm | Ø 16 - 42.4 mm | Ø 16 - 42.4 mm |
| Output vials | up to 4.800 pcs/hr | up to 12.000 pcs/hr | up to 18.000 pcs/hr |
| Format range syringes | 0.5 - 20 ml | 0.5 - 50 ml | 0.5 - 50 ml |
| Output syringes | up to 4.000 pcs/hr | up to 12.000 pcs/hr | up to 36.000 pcs/hr |
| Format range cartridges | 1 - 20 ml | 1 - 20 ml | 1 - 20 ml |
| Output cartridges | up to 3.600 pcs/hr | up to 10.800 pcs/hr | up to 18.000 pcs/hr |
| Suitable for hight potent | Yes | Yes | Yes |
| Loading from depyrogenation tunnel | Yes | Yes | No |

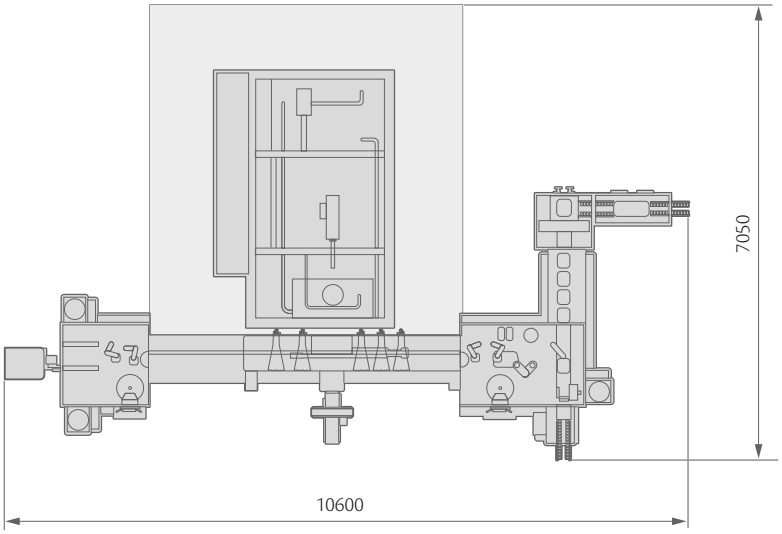
## STERI LIF3
## OPTIONAL UNITS

- Available dosing systems:
  - Volumetric pumps
  - Peristaltic pumps
  - Time/Pressure
- Nitrogen purging:
  - During filling
  - During stoppering
- IPC 100% or statistical
- Vacuum filling
- Vacuum stoppering
- CIP/SIP system
- Pre-arranged for barrier technology.
  Easy integration with cRABS or Isolation System
- 21 CFR Part 11 compliance

STERI LIF3 CONFIGURATION FOR LIQUID PRODUCTS




STERI LIF3 CONFIGURATION FOR LYO PRODUCTS



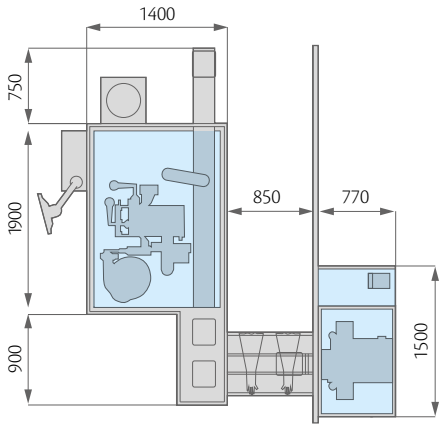

| | STERI LIF3 |
|---|---|
| Automation | Fully robotic automated |
| Footprint | 3.300 x 1.300 x 2.080 [L x W x H] |
| In-Process Control | 100% at full speed |
| RTU vial dimensions | Ø 16 – 42,4 mm |
| Output vials | up to 1.200 pcs/hr |
| RTU syringe dimensions | 0.5 – 50 ml |
| Output syringes | up to 1.200 pcs/hr |
| RTU cartridge dimensions | 1 -20 ml |
| Output cartridges | up to 1.000 pcs/hr |
| Suitable for high potent | Yes |
| Loading from depyrogenation tunnel | No |

# TECHNICAL DATA

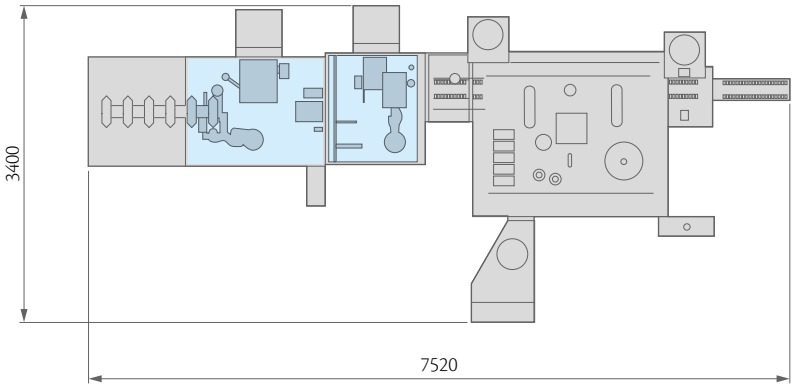
## STERIFILL RS OPTIONAL UNITS

- Automatic extraction and re-insertion of the nest from/into the tub
- Nitrogen gas purging unit
- Vacuum filling system for viscous products to avoid air bubbling
- Statistical and/or 100% IPC
- CIP/SIP system
- Pre-arranged for barrier technology: easy integration with cRABS or Isolation System
- 21 CFR Part 11 compliance

STERIFILL RS-P2 UNDER CRABS




STERIFILL RS-P5 UNDER ISOLATION TECHNOLOGY




| | STERIFILL RS P2 | STERIFILL RS P5 |
|---|---|---|
| Automation | Fully automated | Fully automated |
| Footprint | 2.560 x 1.540 x 2.080 [L x W x H] | 2100 x 1600 x 2.080 [L x W x H] |
| In-Process Control | Statistical | Statistical |
| RTU vial dimensions | Ø 16 - 42,4 mm | Ø 16 - 42,4 mm |
| Output vials | up to 4.400 pcs/hr | up to 10.800 pcs/hr |
| RTU syringe dimensions | 0.5 - 20 ml | 0.5 - 20 ml |
| Output syringes | up to 4.800 pcs/hr | up to 12.000 pcs/hr |
| RTU cartridge dimensions | 1 -20 ml | 1 - 20 ml |
| Output cartridges | up to 3.100 pcs/hr | up to 7.800 pcs/hr |
| Suitable for high potent | Yes | Yes |
| Loading from depyrogenation tunnel | No | No |

ima.it



May 2024 - 991ZS120100

IMA S.p.A. - **LIFE division**
marketing.life.it@ima.it • ima.it/pharma/brands/ima-life
FOLLOW IMA