

Sterile filling of tubes

IWK's latest tube filling innovation is opening up new packaging opportunities for the cosmetic and pharmaceutical industries with their sensitive products and high hygiene standards. The FP Sterile tube filling platform complies with all relevant EDEHG and cGMP guidelines. This new development allows metal, plastic, or laminate tubes to be filled with ointments, creams, and other paste-type media under sterile conditions. The company, a technological pioneer, is thus responding to demands from many pharmaceutical companies for cost-effective packaging solutions that meet more stringent guidelines for filling under sterile conditions. Its attributes also make this new generation of machines highly attractive for the cosmetics industry as they can fill products under sterile conditions, obviating the need for much-criticized preservatives and stabilizers. Consumer demand for these products continues to grow rapidly.

The FP Sterile platform is based on IWK's tried-and-tested FP series, which has enjoyed great success on the market for many years and is used worldwide. Its design and materials have been reworked to facilitate sterile filling. The individual sections of the machine have been modified in line with the contamination risk in each section. The system boasts an output of up to 220 tubes per minute.

Safety as a basic principle

The entire design of the FP sterile platform serves to minimize risks when filling under sterile conditions. It meets all the necessary and relevant EDEHG and cGMP guidelines. Avoiding unsealed openings anywhere in the machine prevents cleaning agents and packaging material from reaching the filling area. Potential 'dead spots' in which residues or bacteria can accumulate and spread are eliminated and critical joints between components, in particular, have been optimized in this respect. All angles between adjacent parts and components are set at 90° or greater and have gapless seals that are approved for filling and cleaning.

There are no parts that could be 'lost' above the open tube and no surfaces that could be contaminated by particles or lubricants. All product contact parts are electropolished and have a surface finish of $\leq 0.8 \mu\text{m}$ as standard. Higher surface qualities are available on request.

Preventing dirt from building up around the system is also a priority. Where possible, electricity is connected via a cable channel in the hall floor. The bottom plate, the tube filler rack and the tube infeed are sealed against the hall floor by a skirt.

Reliable workflow under sterile conditions

The effectiveness of the concept behind this consistent avoidance of contamination is clear right from the point empty tubes are removed from the tray. To ensure that no particles whatsoever can get into an open tube, the gripper only touches the outside

of the empty tubes when placing them on the transport conveyor. In conventional machines, the mandrel dips into the open tube.



Image 1

After the tube has been fed to the tube filler, a sensor carries out tube print registration and, optionally, a camera performs roundness or particle monitoring. The parts and sensors used for these functions, which are also standard in conventional machines, are completely contained within the sterile platform's tube filler, making cleaning easy. Faulty or contaminated tubes are not filled and are ejected further downstream. The user has two options for tube filling, which happens next.

- The ceramic filling system without dynamic seals is designed for filling volumes of up to 50 ml.
- The alternative system with conical rotary valve and dynamic seals permits even greater filling volumes.

Both dosing systems can be combined with CIP/SIP equipment if necessary.



Image 2

When it comes to selecting their tube material, users of FP Sterile have the flexibility of choosing between metal, plastic, or laminate. The machine's modular design means that no conversion work is required, even when changing tube material. Both closure systems – the metal closure and a hot-air one for plastic tubes – can be mounted in parallel and activated as required. The hot exhaust air generated when plastic tubes are sealed is piped away from the machine. All the lines used for sealing air, pneumatics, and the power supply are resistant to cleaning agents.

After sealing, the tube fold can be checked by a camera system, which, like all the cameras and sensors, is integrated into a hygienically designed stainless steel housing. Faulty products are detected and screened, while fault-free products are carefully delivered via a pick and place system to a conveyor and transported to the next packaging step.

The machine is controlled from the stainless steel version of the user-friendly IWK control panel with a 15.4" monitor. Glove ports are mounted at all key points on the machine to enable manual access. This allows, for instance, adjustments to be made without compromising the sterility of the filling area, while interruptions to operations can be greatly reduced or even eliminated completely.

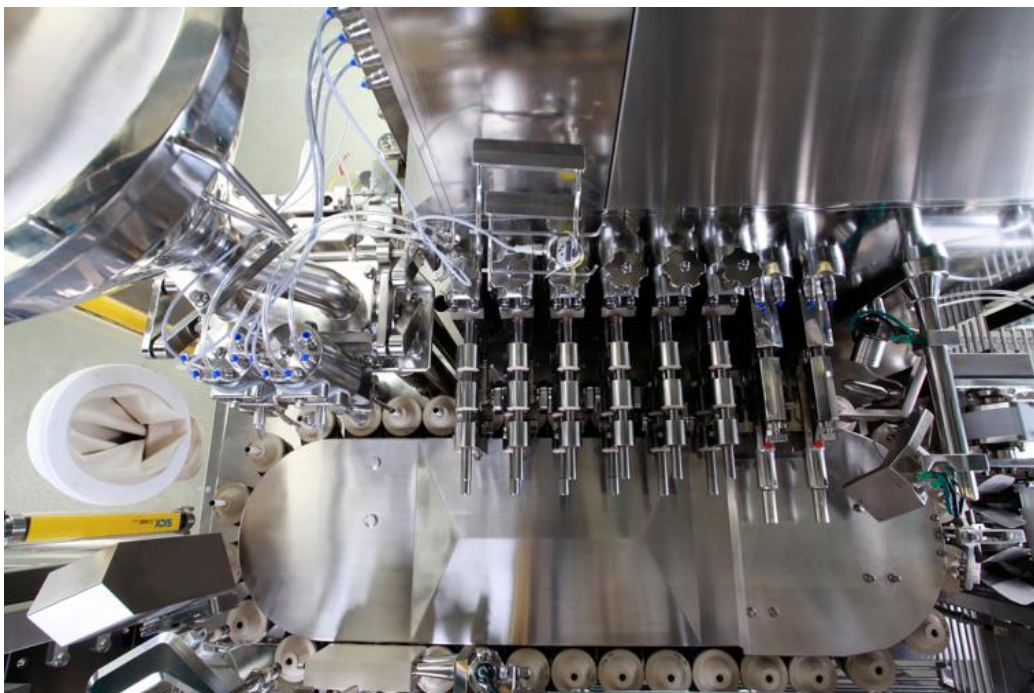


Image 3

A considered choice of materials

In the packaging machine's sterile area, the use of cleaning agents and methods for disinfecting means that materials are sometimes exposed to very tough conditions.

At the same time, the materials used must have as small an area as possible where contamination can build up.

For this reason, only 316L stainless steel with a surface finish of $Ra \leq 0.8 \mu\text{m}$ is used above the table plate, i.e. where the sensitive products are processed. To this end, the steel is thoroughly polished, brushed uniformly, and sanded with grain size ≤ 240 . When the parts are being manufactured, care is taken to ensure that only stainless steel is processed on the production equipment in order to avoid contamination by stainless steel and black material. Metals such as copper and other non-ferrous metals are not used in the machine's work area as a basic principle.

The seals used in the vicinity of the product and on process valves are made of FDA+EMEA/410/01-certified silicones and FPM respectively. Seals in the injection area and outside the vicinity of the product are made of FPM (Viton®).

Format parts with a surface finish of at least $Ra \leq 0.8 \mu\text{m}$ are made of the durable, heat-resistant plastic PVDF (polyvinylidene fluoride) or PEEK polymer. These materials are resistant to high temperatures (up to 130°C in an autoclave) and the cleaning agents used in sterilization.

Sterile production conditions even after batch or product changes

For a product or batch change, all product contact parts can be cleaned and sterilized via the integrated CIP/SIP system without needing to remove and reassemble them. All corresponding valves in the dosing system are activated, monitored, and logged via the control program.

Alternatively, the block of product contact parts can be removed in just a few simple steps and sterilized in an autoclave at temperatures up to 130°C.

The materials used allow the machine surface to be gas-sterilized with hydrogen peroxide (H₂O₂). An alcohol-based rapid disinfection method is usually used.

The FP sterile platform is delivered with all necessary certificates such as: WKZ DIN EN 10204-3.1 for product contact parts, TSE-/BSE-free, sealed seam testing and production certificate for product contact parts, etc.

Captions:

Image 1: Tube infeed gripper, side view of tube skirt

Image 2: Ceramic dosing system

Image 3: FP Sterile transport system viewed from above



About IWK Verpackungstechnik GmbH

IWK Verpackungstechnik GmbH focuses on the efficient, precise, and attractive packaging of goods for the pharmaceutical, cosmetic, food, and chemical industries. IWK systems are used in industries with very exacting standards. The company has been known for its innovative and groundbreaking approach from its very early days. IWK currently holds a large number of patents for key technologies and each year invests significantly above the industry average in research and development, resulting in numerous innovations each year.

Further company information and contact details can be found on the company website at **www.iwk.de**