

STERILE DISPOSABLE INFEED INTO THE ISOLATOR

SteriCon versus Alpha-Beta Ports

Evidently reasons for innovative pharmaceutical manufacturing system must be most compelling. Otherwise, drug manufacturers would not be prepared to leave the path of proven solutions and to accept the enormous initial certifications, efforts and costs. The SteriCon procedure is a very recent approach, but already much in demand, with first projects taking up operation in 2010.

The method of transporting plugs (or other sterile materials) into the isolator by means of a disposable solution has raised keen interest. Below, is a detailed comparison of both systems which place the benefits of the RTP port system under the microscope.

Most striking advantage: SteriCon is the only system for sterile infeed that does not require flange connections for the infeed process. Both components -

the bag as well as the continuous liner - are inserted into each other in multiple overlapping layers according to the SteriCon® system. A modified welding and separation process compounds the bag and the continuous liner, so that the objects inside the bags never come to contact with the outer foil layers. As a result, a beta port is not needed for insertion - but SteriCon can be upgraded on existing RTP ports. (An animation and a video on the functionalities of SteriCon



are available under anfrage@lugaia.ch

Surveys prove: SteriCon is safe

Lugaia STS manufactures the SteriCon bags and the SteriCon continuous liner. Both products are manufactured under ISO class 5 clean room conditions. Traceability of all source materials is ensured and certified by documentation, which forms an integral part of the scope of delivery. Sterilization is achieved either by steam, ETO or gamma rays.

In a study conducted by Optima Group Pharma, the various aspects of pharmaceutical suitability of the SteriCon system underwent stringent analysis. The first aspect of the analysis was the pressure resistance of the peel seam.

▶ **Pressure resistance of the peel seam: max. 500 Pa**

▶ **Bursting strength peel seam and bag: 0.1 bar**

The survey further examined the following three aspects of particle emission

▼ Average particle emission during welding:
15 particles sized > 0.5 µm and
0 particles sized > 5 µm

▼ Average particle emission during peeling-off of a unit NOT having undergone gamma sterilization:
Empty:
8 particles sized > 0.5 µm and
0 particles sized > 5 µm

After the peeling process:
24 Particles sized > 0.5 µm and
0 Particles sized > 5 µm

▼ Average particle emission during peeling-off of a unit having undergone gamma sterilization
Empty:
2 Particles sized > 0.5 µm and
0 Particles sized > 5 µm

After the peeling process:
9 Particles sized > 0.5 µm and
0 Particles sized > 5 µm

The tests were implemented under laminar flow with defined test parameters ¹⁾.

An additional microbiological test carried out by an external organization (according to PP77 incubation of microbiological samples) confirms the system's sterile properties. In this test, gamma-sterilized liner and bags were welded to each other in a non-sterile environment (workshop). Sample evaluation followed after five days.

Here is a literal quote of the laboratory's appraisal:

- All samples without germ growth (no signs of impurities)
- All contact media without germ growth (no visible colony-forming units)
- Sedimentation medium for environment control without germ growth
- All blind samples without germ growth"

- ¹⁾ Test parameters:
- Welding time: 5 s
 - Welding temperature: 160°C
 - Separation time: 6 s
 - Welding temperature peeling seam: 185°C
 - Cooling time: 8 s
 - Pressure (welding jars): 5 bars
 - Volume of samples taken: 28.4 l/min
 - Measuring time: 1 minute ●

	SteriCon	Alpha-Beta-Ports
Used materials	Exclusively PE composites: SteriCon bags and the SteriCon continuous liner (for 300 applications); ready-to-use plugs or ready-to-sterilize plugs.	Bags to a plastic flange (beta port); ready-to-use plugs or ready-to-sterilize plugs.
Production	Simple; reduced material consumption. The SteriCon bag and continuous liner are manufactured at SteriCon under clean room conditions. The SteriCon liner is fitted with the beta port, sealed and then gamma-sterilized.	More material consumption and effort, because a composite connection has to be generated between the foil and the round plastic flange.
RTP port	The SteriCon continuous liner with beta port is docked onto the existing alpha port. Alpha/beta principle only for the SteriCon continuous liner!	RTP port: alpha-beta principle for each feeding process!
Transfer into the isolator	Foil welding: Continuous liner and bag, i.e. two flexible components, are hermitically sealed to each other.	Alpha-beta principle (RTP port)
Profitability	Bag production is comparatively simple and - consequently - relatively cheap (confection line). Costs per bag: approx. 15 Euro Liner with beta port is sufficient for 300 infeed processes. (Beta port can be re-sterilized 20 times.) Investment required for a welding unit	Plastic flange is welded onto each individual bag. Costs: about tenfold 1 beta port per infeed process required Investment required for a different periphery
Certification and safety	- Parameter control system is integrated into the welding system - Optional: Integrated pressure test for each welding process, carried out under sealed connection to the isolator - Studies have confirmed the system's sterility - One-off certification - Safe and easy-to-handle system	- Connection between the continuous liner and the plastic flange is complicated to master - Depending on the pharmaceutical user, up to 100% of the bags are pressure controlled