

process systems

WALDNER
Firmengruppe



isolators and
containments
right from the start



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English

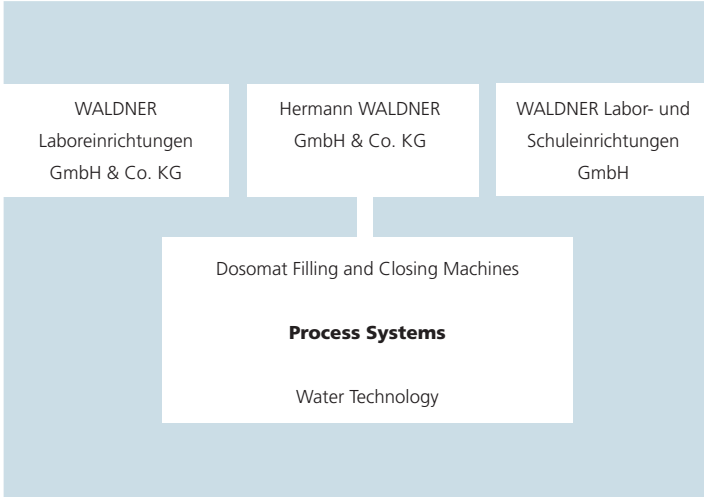


The WALDNER Group - a strong trio

The WALDNER Corporate Group consists of three companies:

- Hermann WALDNER GmbH & Co. KG
- WALDNER Laboreinrichtungen GmbH & Co. KG
- WALDNER Labor- und Schuleinrichtungen GmbH

For nearly one century WALDNER has been setting standards. For the benefit of our customers our business divisions take advantage of our cross-border capabilities. With their size and their involvement in the Corporate Group the three Waldner companies represent stability, expertise and continuity.



Waldner Process Systems

Belonging to Herman Waldner GmbH & Co. KG the business unit Process Systems offers customized procedural solutions for the pharmaceutical, chemical and food industry.

- **Isolators and containments**

Full containment systems for the contamination-free handling of highly active and toxic substances (API) and isolators for sterile applications.

- **Drying technology**

Mobile vacuum contact dryers for dust-free powder handling, vacuum tray dryers conform to GMP standards, intermittent and circulating air tray dryers.

- **Vessels, skids and units**

Vessel technology, ranging from single preparation, pressure and reaction vessels to complete units, container systems, single-layer pressure filters.

- **Cooking systems**

Batch cooking lines for the food industry, for the production of aseptic fruit preparations, jam and many more.

Including the process measuring and control equipment, our products can be combined on the basis of the modular design principle. From competent advisory service on the process development and planning to the realisation of turn-key projects, we provide you with an individual service package that is consequently based on your needs. In short - you obtain what we expect from ourselves everyday: First-class solutions.





isolators and containments **right from the start**

Waldner Process Systems isolators and containment systems in the pharmaceutical

For many years Waldner Process Systems have been manufacturing isolators and containment systems for well-known companies in the pharmaceutical industry. When it comes to the handling of HAPI (highly active pharmaceutical ingredients) routine work in the pharmaceutical R&D and production, like filtration, drying and weighing, becomes difficult. So for this reason isolators are more and more

prevalent in production, laboratories and pilot plants. An isolator separates the active agent and its environment requiring a minimum of space. It replaces expensive clean rooms protecting personnel and product to the same extent. The custom-made Waldner Process Systems isolators and full containment solutions enable safe, flexible and comfortable working conditions.





Smart combinations

Optimum, contamination-free product handling means avoiding interfaces. Combinations between isolators and other Waldner Process Systems apparatuses, as for example pressure vessels, provide new perspectives. Based on the modular design principle, Waldner Process Systems components can be either combined with each other or can be integrated in already existing systems, such as laboratory fume hoods, centrifuges, filters or dryers. An impressive concept. The engineering is clever and sometimes surprisingly straightforward – but always made-to-measure.



Isolators made to measure

Customised isolator systems can be composed of well proven and reliable elements. Here we do not leave anything to chance: Our isolators are ergonomically adjusted to your needs by means of a mock-up model. The isolator is planned on a scale of 1:1. This allows the exact simulation of each process step.

All modules and components are meticulously designed to meet the strictest cGMP and FDA requirements for the production of toxic and biologically active substances.

A diversified range of proven isolator components, including the corresponding automation is available.

- automatic Rapid –Transfer-Port
- Alfa-Beta-Ports
- Waldner continuous liner system
- Push-Push filter systems
- sealing module
- pneumatically sealed front panes / sliding doors
- Glove Tester

Thanks to their excellent cleanability, Waldner Process Systems isolators can be applied for various products. Cross contamination is eliminated, and the systems remain flexible.

Now and in the future: We are there for you

A Waldner Process Systems isolator has an average service life of several decades. A successful, constant collaboration with our customers is our principal goal. Only after perfect integration in your production process do we consider a project a success. Experienced engineers and technicians are at your disposal for the qualification of the isolators (DQ, IQ, OQ) and provide support with validation. The training of your staff, support and advisory service, as well as reliable supply of spare parts is a matter of course to us – in short: Your process optimization takes center stage and our team is at your disposal for all issues concerning your production process. Take us at our word.



The photo shows three production isolators with the well proven rapid transfer port DN 400. The Rapid-Transfer-Containers are approved as hazardous material containers for the transportation by road, sea and air and can be automatically lifted and docked. This is a particular advantage for the handling of large and heavy product quantities.





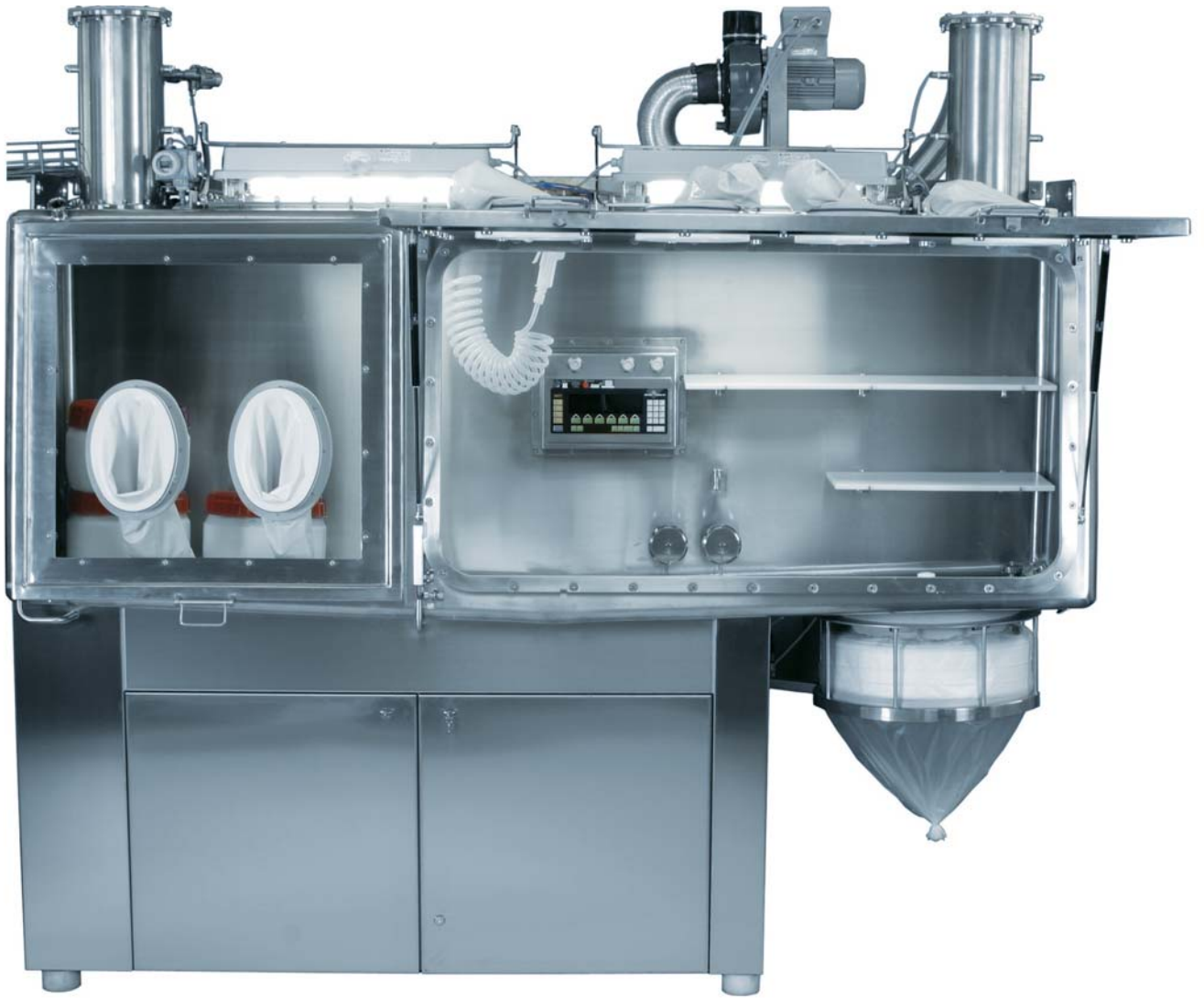
Laboratory isolators

Requiring a minimum of space, the Waldner Process Systems laboratory isolator is a complete system for the researcher: Its equipment ranges from the filtration of the product solution via integrated pressure filter to the drying of the filter cake in the vacuum tray dryer, the weighing with label printer and the outward transfer by means of an Alpha-Beta-Port. The hinged front glass pane also allows open operation if desired. Details, such as the round design of corners and edges as well as ground and polished surfaces, assure excellent cleanability of the entire interior. Providing maximum operator protection, the complete equipment of our compact laboratory isolator is tailored to typical laboratory processes like the filtration, drying and weighing of small product quantities up to 6 litres. The product can be handled under inert atmosphere with operator safety and comfort. Lastly, because of the flexibility of our compact mobile laboratory isolator it can be employed where it is needed. For example, it fits exactly in the modular dimensions of the fume hoods manufactured by our sister company Waldner Laboratory Furniture.

Sterile isolators

When the production of sterile pharmaceuticals demands protection of the product, our sterile isolators are the perfect solution. A typical application is the filling of products that may not be sterilized hot. For such situations the Waldner Process Systems isolator is set under controlled overpressure, furthermore it is equipped with integrated laminar flow systems. In cases of applications with hazardous bacteria, a subsequent biological decontamination can be carried out by means of gaseous hydrogen peroxide or UV radiation. Waldner Process Systems develops customized sterilization cycles that correspond to your application. Our isolators can be combined in various ways: Sterile filling in inliners, sterile discharge of bags into mixers and tanks or combinations with filling machines and filling robots. And last but not least: Waldner Process Systems isolators are especially suitable for the execution of sterility tests.









Rapid- Transfer-Port

The Rapid-Transfer-Port serves as the contamination-free transfer of objects and product into and out of an isolator. The double-lid principle guarantees that the two lids protect one another while open. With this an absolutely contamination-free transfer can be realized.

The Rapid-Transfer-Container (RTC) is docked to the outside of the isolator. Lifting and docking can be carried out by means of a corresponding lifting system. The RTC is automatically locked with the double lid and then opened from the inside. On opening the double lid is tilted towards the inside and so the two lids protect each other against contamination.

The advantages of the RTC are obvious: Apart from their approval as hazardous material containers for the transportation by road, sea and air, they are characterized by their operator convenience and their flexibility. They are very easy to clean, large product quantities can be automatically lifted and docked, and furthermore they can be installed in every position.

Continuous liner system

Product handling inside an isolator and contamination-free outward transfer: Two distinct problems. Waldner Process Systems continuous liner systems serve as the contamination-free outward transfer and simultaneous packing of objects or products that are brought out of an isolator. A film tube magazine with a 80-meter prefabricated continuous liner is installed in the bottom of the glove box. The exiting material is separated by means of a broad weld seam which is cut in the middle, such that a tightly sealed bag is created. Uncomplicated and safe handling was an important principle for the design of the continuous liner system: The film hose magazine cartridge can be exchanged without interrupting the production process and an intelligent system enables the contamination-free exchange of the continuous liner. As an alternative the continuous liner system can be cleaned and rinsed with water. The effluent wash can be drained via a contamination-free drainage.

Glove Tester

The safety of a glove box depends on the integrity of the gloves. Based on a pressure drop test, the Waldner Process Systems Glove Tester checks the integrity of gloves, which are installed in an isolator: After the glove testing lids have been placed in the glove ports they are pneumatically sealed towards the gloves. The test is automatically carried out and the measurement results are recorded with a XY plotter. By means of these results the operator can assess the condition of the gloves. The glove tester is mobile and after the test it is removed from the workspace. The testing lids are safely stored on the Glove Tester. It goes without saying that the Glove Tester meets the highest FDA and cGMP qualifications.





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