

Product Overview

Containment – optimal protection against contamination of employees and product

The times when it was sufficient to develop modern dust extractors and dust masks are long gone.

Effective “**Containment Solutions**” have formed the path for the future. Because with the expanding fields of pharmaceuticals and bio-technology, critical substances are on the rise.

The current state of science, especially in the field of disease control, requires highly active ingredients and substances.

The disadvantage: The concentrations of powders and dusts are getting increasingly more toxic.

With Swiss precision and cutting-

edge technology, Lugaia presents Containment Solutions: producing of flexible packaging and transfer solutions on special, individually developed and linked assembly systems for the safety of your staff and products.

Lugaia offers its customers different security concepts with compliance for required OEL values

Containment Measures	OEL	OEB	Toxic effects
Isolator systems	< 200 ng/m ³	6	Extremely dangerous
	< 1 µg/m ³	5	Very dangerous
Transfer and protective foil systems	1-10 µg/m ³	4	Dangerous
	10-100 µg/m ³	3	Little dangerous
Bag systems with local suction	100-1000 µg/m ³	2	Almost harmless
	> 1000 µg/m ³	1	Harmless

OEL = Occupational Exposure Limit, OEB = Occupational Exposure Band

Lugaia – your specialist for individual unique solutions

No production facility is the same. Almost every containment measure must therefore be individually made and adjusted to the exact conditions. Our production facilities allow for a variety of manufacture types. This enables us to provide practical production and development for customized

solutions entirely according to your wishes. To offer the best possible flexibility, we also provide small series for your development projects.

We will specially develop and adapt to your needs. For example: Containment Solutions for sampling, filter change, and dismantling local encl-

tures for cleaning and maintenance purposes.

We would be happy to advise and help plan together a suitable and innovative solution for your individual problem in terms of containment.

Swiss precision and cutting-edge technology

For innovative and personalized product and personal protection

We are
Lugaia -
video
about us:

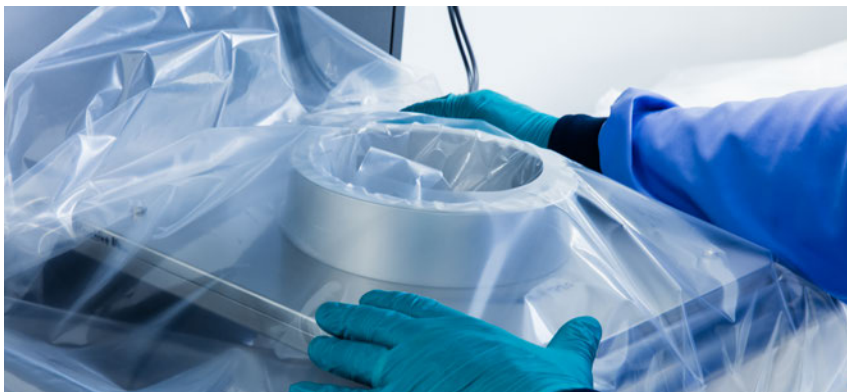


We're directing our focus onto life science, pharmaceutical and bio technology.

Lugaia is pushing the development for the complete Containment Solutions – from the idea of the ergonomic study through to making more complex Isolator Systems.

Our infrastructure enables both standardized products and customized develop solutions to offer different grades in the highest quality of production and means available. Individual products will be continuously evolved to meet the requirements of our customers. Our experience

in the field of containment and sterile technology as well as the steadily growing demands from various industries make up the basis for our continuous innovation processes. In the end, this also guarantees a **"Made in Switzerland"** rating for special precision, quality and reliability.



Quality management systems according to GMP, pharmaceutical, and ISO standards

Clean room infrastructure ISO 5, ISO 7, and ISO 8

Certified according to:
- ISO 9001: 2015
- ISO 15378: 2017



Continuous Liner / Liner Carrier Systems

Continuous Liner System CLS / CLCC



Lugaia Continuous Liner Systems protect employees and products

Flexible and quick



CLS Continuous Liner Carrier

The Continuous Liner System (CLS) is an extremely flexible option when dealing with toxic, highly reactive or pure products.

Through the special RTP Beta-Ports, particularly fast assembly is possible for our CLCC Film Carrier.

The proven axial folding enables foil lengths up to 80 meters.

Fold height and film length are dependent on the film thickness.



CLCC Continuous Liner Carrier

Application areas:

- Pack-off Systems
- Packaging of APIS (Active Pharmaceutical Ingredients) toxic and highly reactive products
- Isolator and clean room application (film lock)
- Primary packaging
- Waste locks
- Material locks
- Sampling



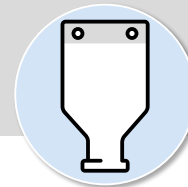
CLS Continuous Liner Packages

The advantages of endless film:

- High product and personal protection in the OEB 5 (<math><1\mu\text{g} / \text{m}^3</math>) Containment-Level
- Easy handling
- Custom foil material possible
- Up to 80 meters per unit
- Less personal protection required
- Reduced or no cleaning of the environment
- Maximum film capacity in the smallest of spaces
- Different diameters and folding heights available
- Film thickness of 50-150 μm
- High quality / manufactured in the clean room ISO 5, ISO 7 or ISO 8

TransferBag Systems

SafePort TransferBag / TransferBag



The SafePort TransferBag – for a safe product transfer

Disposable variant in OEB 5 ($<1\mu\text{g} / \text{m}^3$) Containment-Level



SafePort TransferBag (patented)



TransferBag

The Lugaia TransferBags meet the high demands in the pharmaceutical and biotech areas and are designed for the product transfer of small quantities. The optimal connection option and size of the TransferBags

depends on the application. Standard versions are available in an antistatic film. Upon request, the bags from customer specific foils can also be manufactured in a clean room.

New: Lugaia SafePort Evo - the next generation of secure transfer containment

- **Innovative Design:** 4" single-use TransferBag for continuous docking, seamless product flow without split valve, integrated WIP/CIP cleaning
- **Easy Handling:** Fewer process steps, seals integrated in connection head, no seal build-up, visual positioning guidance
- **High Containment:** Safe handling of hazardous powders with maximum operator and environmental protection
- **Single-Use Efficiency:** No cleaning or validation required, reducing downtime and operational costs



Flexible single-use Isolator Systems

SafeFlex Isolator



SafeFlex Isolator – the flexible solution for closed processes

Customized concepts



SafeFlex Isolator

The SafeFlex Isolators are needs-based and require custom manufacturing. They are particularly suitable for **dispensing, sampling and feeding technology**.

In addition, the flexible and tear-resistant Isolator foil provides optimal features for **manually handling tools**.

Special Features:

- Can be used for applications with negative or positive pressure. Inerting is possible through the additionally available Lugaia Ventilation System
- Feed and remove using a Continuous Liner System
- Docking using double O-ring technology
- Very high OEB 5 ($<1\mu\text{g} / \text{m}^3$) Containment-Level
- Computer based ventilation technology

After the process, in a few simple steps, the Isolator can be disposed of and a new one can be installed. The cleaning and validation efforts are thus reduced.

We offer you the complete one-stop-shop service. From the idea about ergonomic studies to the delivery of the Liner Carrier and Isolator.

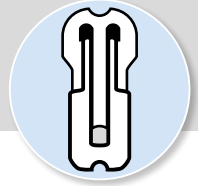


The advantages of the SafeFlex Isolator:

- High product and personal protection
- Easy handling
- Universal usability
- Foil with high tear resistance
- High quality
- Lower investment costs compared to rigid systems
- Elimination of cleaning and validation costs
- Integrable in existing systems
- Gamma or x-ray sterilization possible
- Containment can be done quickly and can be adjusted flexibly afterwards

SafeSeal Closure System (patented)

High containment disposable closure



SafeSeal from Lugaia – simply ingenious or ingeniously simple?

The manual SafeSeal Closure System for Continuous Liner Systems (patented)

The SafeSeal Closure guarantees **OEB 5** ($<1\mu\text{g} / \text{m}^3$) Containment-Level-values in use with Continuous Liner Systems and thus forms the spearhead of manual Closure Systems.

It is manually pulled over the bag, pressed together with the locking pliers and then separated with the help of the special scissor tool. Decisive for the closure size is the

Continuous Liner size and film thickness. Through the use of the SafeSeal Opener, the closure can be removed again without any additional cutting processes.



SafeSeal Locking System

The advantages of the SafeSeal Closure System:

- Easy handling
- High occupational safety
- Universal usability
- Low investment costs
- High quality
- Axial locking mechanism
- Guaranteed OEB 5 ($<1\mu\text{g} / \text{m}^3$) Containment-Level
- 3 different sizes
- Can be expanded with Protective Cap and Hanging System

The components of the SafeSeal Closure System:



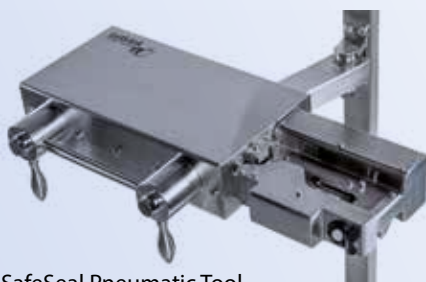
SafeSeal Crimp (3 sizes S, M, and L)



SafeSeal Toolset: ratchet scissors and locking pliers



SafeSeal DuoPro



SafeSeal Pneumatic Tool



SafeSeal Opener in 3 sizes (S, M and L)



SafeSeal Protective Cap and Hanging System



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