DE LAMA

LEADING EDGE TECHNOLOGIES BOOK

January 2024

TECH OF THE FUTURE ...
... ALREADY HERE

De Lama *HyPerPure*®
Low temperature H_2O_2 sterilization technology
under deep vacuum & zero air

De Lama Magnetodoor®
Magnetic driven door
for Pharma equipment

Isolator direct connection
With autoclave or autoclave+washer
combined unit through Magnetodoor®

De Lama DLTI
Low temperature & high-precision equipment

INNOVATION 1

De Lama HyPerPure® Sterilizer with H_2O_2 and Zero Air

Low temperature sterilization

THE MOST ECO-FRIENDLY STERILIZER EVER

- energy saving
- water saving
- eco-friendly media exaust

INNOVATION OVERVIEW

De Lama has developed an innovative process starting from its many years of experience in the sterilization field: **HyPerPure® Low temperature Sterilization technology with Hydrogen Peroxide under deep vacuum and zero air.**

HyPerPure® Sterilization technology is a proprietary solution by De Lama operated with De Lama DLVHP/ST equipment with **built-in patented De Lama HyPerGeneSys® H_2O_2 generator**.

It's a **low-temperature sterilization** process representing the **real alternative to EtO (Ethylene Oxide) and Gamma Rays sterilization**, and offering important advantages compared to these more traditional techniques.

Thermo-labile and non-thermo-labile products can be **fully sterilised in the most recessed cavities.** The peculiarity of the use of the vacuum technology allows gas full penetration into the widest variety of packaging.
Vacuum system is composed of a multiple step high vacuum system to allow the most effective sterilization phase and gas removal at cycle end. This equipment in addition to thermo-labile products can treat most of products that previously could be treated with traditional techniques such as steam sterilization. The advantages are enormous in comparison with EtO and steam sterilization.
The sterilisation cycle work in an open loop, **without any consumable, and grant a very high level of repeatability**

Due to the **very low energy consumption** this sterilizer is the best option for a Company to **reach ZERO CARBON TARGET.**

PATENTED HyPerGeneSys® H_2O_2 GENERATOR

PRODUCTS THAT CAN BE TREATED:

ALL PRODUCTS THAT CAN BE TREATED WITH CLASSIC STEAM STERILIZER EXCEPT LIQUIDS AND MATERIALS WITH A NON COMPATIBILITY WITH H_2O_2

Garments and textiles

Glasswares and vials

Surgery tools and metal tools

Machine parts

THERMO-SENSITIVE PHARMA OR MEDICAL PRODUCTS

PHARMA

Nest with syringes

Packaging of pre-filled syringes

Single use parts of the filling line

POM-C transfer parts of the filling line

MEDICAL

Catheters and intracardiac catheters

Surgery kit

Prosthesys for implant

Electronic medical devices (peace-makers, cochlear implants)

ADVANTAGES IN COMPARISON WITH EtO (Ethylene Oxide) STERILIZER

- faster process. 3-6 hours against 48 or more hours of overall Ethylene Oxide process
- no need of ancillary devices like, pre-conditioning chambers, post-conditioning chambers, burners with subsequent space saving and investment saving
- H_2O_2 is not explosive as ETO: authorizations connected with explosive media are not needed
- H_2O_2 media is not cancerogenic as ETO
- very low H_2O_2 consumption. Cost of media x cycle H_2O_2 vs EtO about 10 times lower
- HyPerPure® sterilizer is not a pressure vessel: there is no need of certifications
- can be easily internalized inside company

GENERAL ADVANTAGES

- very low energy consumption
- is not a pressure vessel
- fast process
- economical process
- no use of consumables (except H_2O_2 media)
- the 'greenest' sterilizer on the market yet
- low energy consumption makes it the best sterilizer choice for a Company to reach Zero Carbon Target

INNOVATION 2

De Lama Magnetodoor® magnetic driven door

SUITABLE FOR STANDING ALONE EQUIPMENT OR EQUIPMENT CONNECTED WITH ISOLATOR

INNOVATION OVERVIEW

De Lama has developed **Magnetodoor® (registered trademark and PATENT PENDING)**: a new sliding door concept where the door movement is achieved through magnetic coupling. This design **minimizes the dirt retention areas** in the bioseal and allows access to the inner side of the door.
This door is now **available for all De Lama autoclaves, washers, ovens, decontamination units and combo equipment (as washer + sterilizer 2 in 1 unit).**

ADVANTAGES

- makes De Lama **autoclaves, ovens, washers or combo units now directly integrable with an isolator,** eliminating all problems connected to the transfer of sterilized products inside and outside the isolator itself
- the **door is 100% compatible with H_20_2 sanitization** inside isolator
- the whole **inner door side is now directly accessible** for direct **manual cleaning**
- door sliding mechanism is **minimized to the essential parts**, reducing the number of components and their future possible replacement and maintenance costs
- **no particle release** in the environment due to the absence of toothed belts, gears, motors etc.

INNOVATION 3

Isolator direct connection through De Lama Magnetodoor®

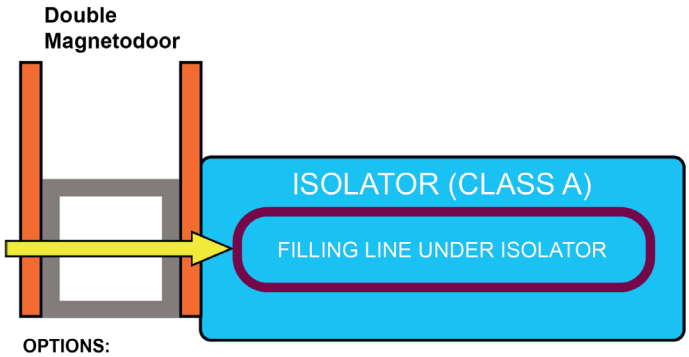
INNOVATION OVERVIEW

De Lama is the only manufacturer in the world to present the door slinding mechanism with magnet: De Lama **Magnetodoor®**. Such design is the perfect solution for a direct integration with an isolator where cleanability, reduced footprint and sanitization with H_2O_2 are a paramount.

ADVANTAGES

- **door sliding** instead of hinged design **minimizes the isolator space devoted to the integration** with the equipment (no clearance for the door swinging)
- the magnetic sliding **minimizes the number of components and materials** positioned on the isolator side reducing the risk of dirt retention
- the limited number of components and the clean design of the door **allow the full sanitization and compatibility with H_2O_2 during the isolator inner treatment**

CONFIGURATION 1
CONNECTION OF DE LAMA EQUIPMENT (AUTOCLAVE AND/OR WASHER) WITH THE ENTRANCE OF ISOLATOR



OPTIONS:
- Steam Sterilizer
- Dry Heat Sterilizer
- Hydrogen Peroxide sterilizer under deep vacuum
- Combo washer + sterilizer
- Hydrogen Peroxide Pass-box

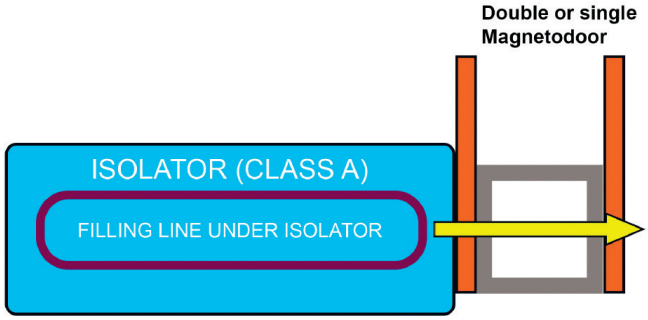
This configuration provides a double Magnetodoor® that allows you to load the items into the sterilizer and unload the sterilized items directly into the isolator, thanks to the presence of a tight connection between the two devices.

The peculiarity of this configuration is its flexibility, as it can be easily adapted to specific process requirements.

Indeed, the sterilizer can be one of the following options: steam sterilizer, air, steam sterilizer, dry heat sterilizer, HyPerPure® technology for low temperature sterilization under high vacuum or equipment that combines washer and steam sterilizer, washer and HyPerPure® sterilizer .

Depending on the choice of the sterilizer, this configuration can be applied, for example, to the following operations, which are required for the aseptic processing of various items: washing and steam sterilization of the heat-resistant parts of the aseptic line, to be used in the isolator, where the filling process, depyrogenation of the containers is carried out, which must be used inside the isolator

CONFIGURATION 2
CONNECTION OF DE LAMA EQUIPMENT (AUTOCLAVE AND/OR WASHER) WITH THE EXIT OF ISOLATOR



TERMINAL STERILIZATION:
Steam sterilizer
Air/Steam Mixture sterilizer

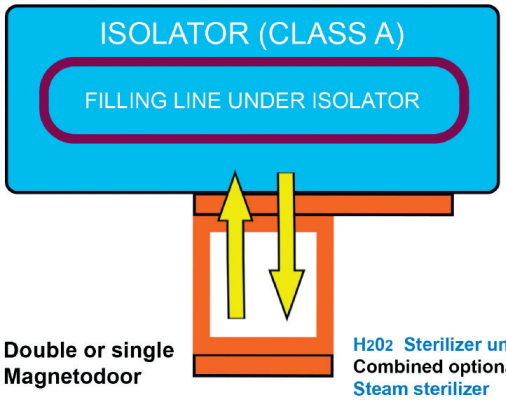
This configuration includes a double Magnetodoor ® that connects the unloading side of the isolator with the sterilizer. This would allow the items to be directly downloaded from the isolator into a sterilizer, thanks to the presence of a close connection between the two devices.

Also in this case a flexibility of application of this configuration is maintained, taking into account that the sterilizer can be a steam sterilizer, an air/steam mixture sterilizer or a HyPerPure ® low temperature sterilzer with Hydrogen Peroxide under deep vacuum and zero air.

For example, when the isolator is connected to a HyPerPure ® sterilizer, this solution allows the terminal sterilization of sealed packages containing heat resistant or heat sensitive products, after their aseptic treatment inside the isolator.

The same advantages described for Configuration 1 can be reported: reduction of risk of contamination, space saving, optimization of process flow.

CONFIGURATION 3
CONNECTION OF DE LAMA EQUIPMENT (AUTOCLAVE AND/OR WASHER) WITH THE ISOLATOR SIDE AS A PENINSULA



H2O2 Sterilizer under vacuum
Combined optionally with:
Steam sterilizer
or/and
Washer

This configuration includes a single or double Magnetodoor ®, which connects the sterilizer with an alternative loading/unloading side of the isolator.
This configuration was conceived considering any need to move items from the isolator into a sterilizer and back into the isolator when the sterilization process is finished.

Depending on the requirements of the aseptic process, the sterilizer can be, as in the previous configurations, a steam sterilizer, an air/steam mixture sterilizer, a dry heat sterilizer, a HyPerPure ® high vacuum peroxide sterilizer or an equipment that combines in one single unit a washer and a steam sterilizer or a washer with a HyPerPure® sterilizer with Hydrogen peroxide under high vacuum.
The particular application of this configuration is for moving auxiliary items, which are used in processing (e.g. in a filling line installed inside the isolator) directly from the isolator chamber into a sterilizer or washing machine combined with a sterilizer, without the need to remove them from the isolator in the clean-room. This direct connection allows items to be returned to the same isolator as soon as they have been sterilized.

The main advantages of this configuration lie in the reduced space requirement in the clean room, an optimization of process operations, always keeping the risk of contamination low, and using the direct connection between sterilizer and isolator via a Magnetodoor®.

INNOVATION 4

De Lama DLTI.
Low Temperature & High Precision equipment

REACHING WHAT SEEMED TO BE IMPOSSIBILE: + - 0,5 DEGREE CONTROL

INNOVATION OVERVIEW

DLTI is a brand new equipment designed and developed by De Lama for those **products that must be treated at low temperatures** but at the same time require a process with **very high thermal precision.**
The plant is able to operate in a variable temperature band**, from 40 ° to 85 ° degrees celsius.**

De Lama has developed an exclusive process that allows it to comply with **thermal parameters with a maximum variation of + – 0,5 degrees.**

The DLTI is available in the **DLTI/A configuration with air action in the event that the product cannot come into contact with humidity,** and in the **DLTI/S configuration where the process is carried out using saturated steam when there is no problem in case of product contact with water.**

ADVANTAGES

Now it is possible to treat super-sensitive products requiring an extreme level of thermal precision.
This thermal precision is in fact impossible to achieve with the traditional ovens that De Lama offers in its DLST/L Series.

INNOVATION 5

Innovative washing solutions

THE 1st DOOR FOR WASHER
100% MADE OF GLASS,
WITHOUT ANY STEEL FRAME

INNOVATIONS OVERVIEW

De Lama washing line offers several innovative solutions.

De Lama has been the 1st company to offer **100% customization in the equipment design process,** also starting by **manual laser scanning for single products to be treated.**

Starting from the scan of single parts De Lama can:

- design a **custom trolley** where **every single part can find it's own perfect position**. In this way we verify the **perfect water coverage** througt **computer simulation** and we can assure total **repeatability**
- following the trolley customization, then **the chamber size and shape are customized**
- De Lama can also customize size and shape according to the Customer's need
- De Lama can remote the technical cabinet (washing skid with water pump and detergents) also putting it above the rooftop or in the down-floor.

Another **innovation to improve cleanability** is the exclusive **100% glass door, without any steel frame**, in order **to avoid any dirt retention.**

INNOVATION 6

Innovative decontamination solutions

PASS-BOX FOR DECONTAMINATION WITH VAPORIZED H_2O_2 & AIR DEGASSING

SPECIAL FEATURES & ADVANTAGES:

- **100% frameless glass doors** (to avoid any dirt retention)
- The **glass doors are electrically heated** to **avoid any peroxide condensation**
- **Patented HyPerGeneSys® 'built-in' Vaporized H_2O_2 generator** with **ionization** of peroxide molecules
- **Ionization** allows to **increase the oxidizing action** of the peroxide up to 20%, making the process safer and faster
- **Total customization** of capacity and shape
- Possibility of reducing the footprint by **remoting the technical compartment**
- **Metal oxide catalytic filter** without consumables
- Use of commercially available peroxide, at 35%

PASS-BOX FOR DECONTAMINATION WITH VAPORIZED H_2O_2 PEROXIDE& VACUUM DEGASSING

SPECIAL FEATURES & ADVANTAGES:

- **No impact on HVAC systems**. The degassing is carried out through the vacuum pump instead of the 'traditional' air flows that determine an important impact on the company aeration system.

  The pass-box can therefore be inserted into the company even after the plant has been designed or is already **operational**.
- **Ultra-fast process, especially for porous materials:**, can last even less than 1 hour
- **Patented HyPerGeneSys® 'built-in' Vaporized H_2O_2 generator** with **ionization** of peroxide molecules
- The construction of the chamber, conceived as a pressure vessel, allows it to hold the vacuum and pressure tests like no traditional peroxide pass-box.

  In particular, the DLVHP / De can perform:

  Vacuum test up to 70 abs mbar

  Pressure test up to 0.45 bar
- No consumables: **savings in costs and management time.** No HEPA filters, carbon filters etc.

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