Telstar

# Pura Sterility Test Isolators


Technology. Science. Life.

As an international leader focused on Quality, Telstar partners with clients to provide technically advanced solutions on a global basis through innovation, absolute reliability and expert project management.

Providing in-house expertise in design (strengthened with 3D design skills) and manufacture of innovative/ bespoke Barrier Isolation equipment, which requires research and development skills on a day-to-day basis.

Telstar strives continuously to address and adapt to ever changing industry needs, evolving inline with government regulations and stringent industry standards.

## Recognised Leaders in Sterility Testing Technology

Telstar rises to demands in pharmaceutical Aseptic and Containment Barrier Isolation equipment, providing solutions for specific challenges presented by clients' individual requirements.

Sterility Testing is an ever more important part of any pharmaceutical process. A clear understanding of the process is paramount to its success.

Telstar Life Sciences UK Ltd, is the centre of excellence for the Aseptic and Containment Barrier Isolation side of the Telstar business and are fully aware that attention to detail makes all the difference when designing the right solution.

**A leading pharmaceutical company** report stated almost 25% of all lost time illnesses were caused by ergonomic related issues.

Telstar put great emphasis on the need to perform ergonomic trials, at the onset of all projects, to identify issues and prevent them becoming a problem. Models together with trials serve to simulate the process operations involved.

This process has already been extensively performed in the development of the Telstar Pura range of Sterility Test Isolators, resulting in an ergonomically designed range.

Supported by continual investment in 3D software technology operated by design personnel from a highly qualified engineering background. 3D design provides a clearer visualisation of the entire project preventing clashes and accurate production of 2D drawing elevations.

## A comprehensive range protecting the most critical step in the production process.

Sterility testing of sterile pharmaceutical products is required by the Pharmacopoeias to determine acceptability of a production batch. It is an essential element of sterilisation validation and it must be performed in a manner which avoids the risks of both false positive and false negative results.

False positive results are generally due to laboratory contamination from the testing environment or technician/technique error and cause additional work in terms of extra documentation required and adds significantly to cost as it delays or prevents release of the product for sale.

Telstar Pura Sterility Test Isolators are designed to avoid the risk of false results and to protect the product from both the process and externally generated factors that would compromise its quality.

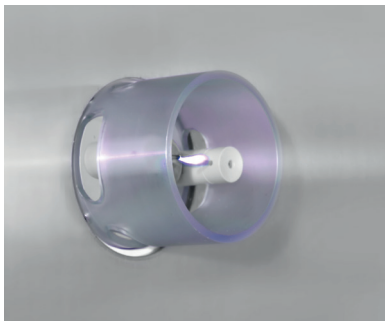
The Telstar Pura range has been developed to cover a wide range of client's needs. The units' ability to provide a reliable aseptic environment for sterility testing and other aseptic processes is unquestioned. A minimum of log 6 reduction in spore forming micro-organisms is consistently achieved & validated using a BI challenge.

The Telstar Pura range is suitable for performing both Direct Inoculation and Filter Membrane sterility tests with flexibility to be bio-decontaminated by different types of systems available.

The Telstar Pura Sterility Test Isolator complies fully with ISO 14644-7:2004 producing an EU GMP Grade A environment throughout the chamber.

## ionHP+

Following extensive research Telstar UK has identified an alternative decontamination system, using (ionized Hydrogen Peroxide) ionHP+.



This bio-decontamination system is an integrated decontamination system dedicated to a single Sterility Test Isolator.

This unique system provides rapid and effective sterilisation of the Isolator and is proven technology giving a six log reduction of viruses, spores and fungi.

The system produces a fine mist of hydrogen peroxide and isopropyl alcohol by passing through a cold plasma arc to ionize the medium. Once ionized it acts like a gas providing excellent distribution and due to its positive charged properties reaches those hard to reach areas. This in turn reduces the sterilisation times over alternative methods.

The ionHP+ system is controlled via the Isolator PLC based control system and includes complete data acquisition and H202 chamber monitoring.

## The ionHP+ Advantage

- ✓ Superior efficacy
- ✓ Rapid response and reduced cycle times
- ✓ Reduced Sterilant quantities
- ✓ No excessive temperature rise during cycle
- ✓ Temperature & Humidity has no effect on the cycle
- ✓ Excellent materials compatibility
- ✓ Minimized downtime
- ✓ Environmentally-friendly ('green')
- ✓ Cost-effective pricing

# Telstar Pura Sterility Test Isolator range:

**Telstar's Technical Sales Team will work with you to identify your exact requirements for your Sterility Testing Isolator.**

**Telstar Pura 2**

Single Chamber Isolator with 2 gloves.

**Telstar Pura 3**

Single Chamber Isolator with 3 gloves.

**Telstar Pura 4**

Single Chamber Isolator with 4 gloves.

Telstar Pura 2, 3 & 4 are for small scale sterility testing and choice of model is dependent on the number of tests to be performed. These Isolators are designed for single batch sterility testing; the Isolators are pre-loaded with samples and test materials before bio-decontamination. After bio-decontamination the batch is tested and then the Isolator is closed down at the end of testing.

**Telstar Pura 3+**

Double Chamber Isolator
(main chamber with 3 gloves + transfer chamber).

**Telstar Pura 4+**

Double Chamber Isolator
(main chamber with 4 gloves + transfer chamber).

Telstar Pura 3+ & 4+ are used for continuous batch testing where large numbers of sterility tests need to be performed. The Isolator is pre-loaded with the initial samples and test materials before bio-decontamination, after bio-decontamination the sterility testing can proceed. Additional functionality with these Isolator models is that additional test materials and samples can be introduced and bio-decontaminated via the transfer chamber whilst sterility testing is taking place in the main chamber. The sterility testing process can then be continuous; transferring samples and test materials into the Isolator without detriment to the working environment.

## Key features and benefits:

- Positive pressure with alarm set points to avoid any product contamination.
- Single pass turbulent flow (EU GMP grade A) to maintain sterile conditions inside the Isolator.
- The glass vision panels are 'gull wing' type which hinge upwards and outwards. In the open position the doors are held open with gas struts.
- Inflatable seal technology on all doors assures very low leakage rate in compliance with the most stringent leakage criteria stated in ISO 14644-7.
- High resistance to H202 without giving rise to excessive out gassing and thus minimising bio-decontamination cycle time.
- Design suitable for bio-decontamination using a broad range of systems to fulfil user requirements.
- Integrated or stand alone bio-decontamination system or unique Telstar ionHP+ system.
- PLC based user friendly automated control with automatic leak test function (pressure hold test).

## As standard the units include:

- Internal temperature & humidity monitoring sensors.
- Oval shaped gloveports designed for sound ergonomic posture whilst maximizing operator arm movement.
- Gloves are a three part design which enables changing of a glove without compromising Isolator sterility.
- Grade AISI 316L stainless steel, fully welded, crevice free with smooth internal surfaces guarantees complete cleanability.
- Support frame manufactured from AISI 304L stainless steel.
- Lighting fixtures within each chamber with external access for maintenance.

## Main advantages of using an Isolator for Sterility Testing

- No requirement for a cleanroom environment surrounding the Isolator
- Reduced cost by not having to maintain and operate surrounding cleanroom
- Reduced operating cost with no gowning requirements for technicians, cleaning, sterilising and time to gown and de-gown
- Removal of the main cause of contamination (operators) from the testing area
- Significant reduction in the risk of false-positive results and the corresponding savings for investigations and product release delays
- Increased capacity for sample analysis
- Enhancement of compliance with domestic and international guidelines and expectations

# Options available for the Telstar Pura Sterility Test Isolator range:

## Factory Fitted Options

- Bio-decontamination System
- Sterility Test Pump
- Glove Tester
- Paperless Chart Recorder
- Automated raise/lower Support Frame
- H202 external Monitoring Sensor
- Alternative types of Transfer Ports
- Internal Shelving & Racking

## Ancillary Options

- Non Viable Monitoring
- Viable Monitoring
- Continuous liner Grommet for Gamma Irradiated liners or bags
- Continuous Liner bag welder
- Bag Welder mobile trolley

## Fully Compliant

Telstar Pura Sterility Test Isolators are guaranteed to comply with relevant standards and demands set by the regulatory bodies to ensure conformance and client's satisfaction, including:

- FS 209E Airborne Particulate Cleanliness
- cGMP Guidelines (current Good Manufacturing Practices)
- ISPE Guidelines (The Society of Pharmaceutical and Medical Device Professionals)
- FDA (Food and Drug Administration)
- MCA (Medical Control Agency)
- American Glovebox Society Guidelines

Telstar provides a comprehensive validation service to clients providing FAT/SAT/DQ/IQ/OQ & PQ protocols if required.

Additionally Telstar UK has a dedicated Customer Service division who offer a complete package to ensure your equipment is working correctly and efficiently at all times.


**The production site where the products are made has been assessed and given ISO 9001:2008 approval**

**All equipment is manufactured to allow it to be CE marked in accordance with 98/37/EC Machinery Directive.**

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Check for the nearest Telstar office at www.telstar.com/international

Av. Font i Sagué, 55 · 08227 Terrassa (Spain) | T +34 937 361 600 | telstar@telstar.com | www.telstar.com

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