Telstar Aseptic Barrier Isolation Systems

Designed for sterile-product and Parent API’s either with line or at high GMP environment. Design covers may be unidirectional or turbulent, interfaced with H2O, air or nitrogen. Pressure distribution is internal to the Isolator.

- Automatic Interface
- Liquid & Powder Filling (vials & trays)
- Gas/liquid hand loaded & load-out

Mobile Transfer Systems

- Over bagging & Heat Sealing
- Bunging / Stoppering / Crimping
- Bulk Powder Filling (into kegs)
- Dirty Tray transfer, Wetting & Removal
- Product Transfer
- Lyophiliser Auto Load & Un-Load
- Liquid & Powder Filling (vials & trays)
- Autoclave Interface
- Multiple Decontamination Options
- Sterility Testing
- Over bagging & Heat Sealing
- Bunging / Stoppering / Crimping
- Bulk Powder Filling (into kegs)
- Dirty Tray transfer, Wetting & Removal
- Product Transfer
- Lyophiliser Auto Load & Un-Load
Attention to detail makes all the difference when designing the right solution. Telstar Life Sciences UK Ltd, is the centre of excellence for the Aseptic and Containment Barrier Isolation technology of Telstar. Paramount to its success.

Aseptic Barrier Isolation is an ever more important part of any pharmaceutical process. A clear understanding of the process is challenges presented by clients’ individual requirements.

Telstar rises to demands in pharmaceutical Aseptic and Containment Barrier Isolation equipment, providing solutions for specific needs, evolving inline with regulatory authorities and industry standards.

Recognised Leaders in Aseptic Technology
Telstar rose to demands in pharmaceutical aseptic and containment barrier isolation equipment, providing solutions for specific challenges presented by clients’ individual requirements.

Aseptic Barrier Isolation 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 technology of Telstar. 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.

Supported by continual investment in 3D software technology operated by design personnel from an engineering background.

3D design provides a clearer visualisation of the entire project preventing clashes, resulting in accurate production of 2D drawing elevations.

Telstar hallmark at every stage:
- Expert attention to detail and complete understanding of the process.
- Evaluating and understanding process equipment operators, containment, ergonomic issues and inorganic environmental trials are critical elements to success.
- Identifying critical issues and preventing potentially costly problems before they occur.

Telstar provides complete systems, integrating high quality barrier systems with either Telstar process equipment or third-party devices.

If required Telstar’s systems can be designed to fully interface with Telstar or third party Lyophilisers, loading/unloading systems and robotic arms to fully automate processes.

Full mechanical and software integration of a robotic arm automates the transfer of empty trays from the entry door, places them on the ATLUS loading unloading frame and fills them with liquid product for loading into the freeze dryer. The robotic arm is also employed to retrieve the trays containing the freeze dried product from the ATLUS frame after unloading from the freeze dryer, placing them on the exit-out feed conveyor for automated transfer to the vacuum transfer chamber.

Aseptic bulk product pack-off line
Bulk product contained in a BIC can be blended on a post hoist or dedicated conical blender prior to pack-off.

Final product is filled, crimped and sealed into aluminium bags.

Vacuum transfer chamber
Operations work through glasses using a vacuum lane to aseptically transfer the freeze dried product from trays, via a high efficiency, cyclone transfer system mounted on a frame above the existing HPLC.

Robotic Arm
Full mechanical and software integration of a robotic arm automates the transfer of empty trays from the entry door, places them on the ATLUS loading unloading frame and fills them with liquid product for loading into the freeze dryer. The robotic arm is also employed to retrieve the trays containing the freeze dried product from the ATLUS frame after unloading from the freeze dryer, placing them on the exit-out feed conveyor for automated transfer to the vacuum transfer chamber.

Steriliser Interface
Aseptic interface with the tray sterilising tunnel, featuring an automated pneumatic door and reliable seal.

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Telstar provides complete systems, integrating high quality barrier systems with either Telstar process equipment or third-party devices.

If required Telstar’s systems can be designed to fully interface with Telstar or third party Lyophilisers, loading/unloading systems and robotic arms to fully automate processes. For example liquid product tray filling prior to the freeze drying process.

To facilitate liquid product transfer and pack-off following the freeze-drying process we are able to provide highly successful solutions implementing high efficiency cyclone vacuum devices coupled to BIC’s, post hoist/conical blending and BIC filling. Automated weighing, sampling and filling systems provide end product pack-off to clients choice of containers.

Additionally, Telstar barrier systems can be designed to provide aseptic barriers between the operator and other process equipment including PLC/platforms, washing machines, autoclaves and sterilising tunnels.

Illustrations showcase Telstar’s global capability, which is achieved by close collaboration between Telstar’s global centres of excellence. The barrier systems expertise is proven by Telstar’s Life Science UK division located at Dewsbury in the UK.

Aseptic bulk product pack-off line
Bulk product contained in an BIC can be blended on a post hoist or dedicated conical blender prior to pack-off.

Final product is filled, crimped and sealed into aluminium bags.

Vacuum transfer chamber
Operations work through glasses using a vacuum lane to aseptically transfer the freeze dried product from trays, via a high efficiency, cyclone transfer system mounted on a frame above the existing HPLC.

Robotic Arm
Full mechanical and software integration of a robotic arm automates the transfer of empty trays from the entry door, places them on the ATLUS loading unloading frame and fills them with liquid product for loading into the freeze dryer. The robotic arm is also employed to retrieve the trays containing the freeze dried product from the ATLUS frame after unloading from the freeze dryer, placing them on the exit-out feed conveyor for automated transfer to the vacuum transfer chamber.

Steriliser Interface
Aseptic interface with the tray sterilising tunnel, featuring an automated pneumatic door and reliable seal.

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- Expert attention to detail and complete understanding of the process.
- Evaluating and understanding process equipment operators, containment, ergonomic issues and inorganic environmental trials are critical elements to success.
- Identifying critical issues and preventing potentially costly problems before they occur.
Telstar Aseptic Barrier Systems are supplied with PLC control platforms supported by the latest software and Human Machine Interface. The HMI provides full integration with the process equipment.

- Purpose-designed screens ensure Telstar systems are user-friendly, whilst availability of password management according to client protocols and company quality procedures allow secure access, simplicity of operation and is easy to decontaminate.

- The active port can be used with a passive canister or bag-in/bag-out grommet connection. The purpose of the port is to allow aseptic transfer of materials to and from the Isolator or waste out of the Isolator in a controlled manner, ensuring the integrity of the Isolator’s internal environment remains intact at all times.

- Telstar’s standard range of five Sterility Test Isolators are designed to accommodate the rising demand within the Pharmaceutical industry and can be supplied with various industry standard decontamination generators according to choice.

- Telstar also offers its own in-house plasma charged bio-decontamination system, which was developed by Telstar for use in Isolators, providing a unique cost effective alternative. For more information on this range please refer to Telstar’s dedicated brochure available for download from the website.

Fully Compliant

Telstar Aseptic Barrier Systems are guaranteed to comply with relevant standards and demands set by the regulatory bodies to ensure conformance and clients satisfaction, including:

- ISO 3644/1: Cleanroom & Associated Controlled Environment
- ISPE (International Society for Pharmaceutical Engineering)
- FS 209E Airborne Particulate Cleanliness
- MCA (Medical Control Agency)
- FDA (Food and Drug Administration)
- American Pharmaceutical Granules
- American Gaseous Society Guidelines
- Telstar provides a comprehensive validation service to clients providing FAT/SAT/DQ/IQ/OQ & PQ protocols if necessary.

Telstar Aseptic Barrier Isolation Systems

- Designed for sterile product and Parent API’s either with or at high GMP environments. Telstar systems may be unidirectional or turbulent. Interfaced with H2O2 decontamination generators according to choice.
- The production site where the products are made has been assessed and given ISO 9001:2008 approval.
- The active port can be used with a passive canister or bag-in/bag-out grommet connection. The purpose of the port is to allow aseptic transfer of materials to and from the Isolator or waste out of the Isolator in a controlled manner, ensuring the integrity of the Isolator’s internal environment remains intact at all times.

- Telstar contained transfer system (CTS), independently tested to below 5 nanograms offers ultimate safety, simplicity of operation and is easy to decontaminate.

- Aseptic Barrier Isolation Systems

- Designed, manufactured and supplied - high quality integrated systems offering:
  - Increased efficiency
  - Automation
  - Flexibility
  - Protected critical zones
  - Environment line from pathogenic micro-organisms
  - Custom systems both large & small designed to specific client requirements operating at positive pressure and having controlled environmental conditions.

- The active port can be used with a passive canister or bag-in/bag-out grommet connection. The purpose of the port is to allow aseptic transfer of materials to and from the Isolator or waste out of the Isolator in a controlled manner, ensuring the integrity of the Isolator’s internal environment remains intact at all times.

From full filling lines to stand alone single Isolators, barrier systems are designed to provide solutions adhering to regulatory standards and guidelines. Running at positive pressure during normal conditions with auto change to negative in the unlikely event of system breech, when toxic products are involved.

- Mobile transfer systems/carts are available with dedicated air handling capabilities. Providing a SO2 aseptic environment the cart is complete with a shell inducing arrangement for the loading/unloading and transfer of sterile trays from the tray sterilising tunnel to the process Barrier/Isolator.

- Mobile transfers are available with dedicated air handling capabilities. Providing a SO2 aseptic environment the cart is complete with a shell inducing arrangement for the loading/unloading and transfer of sterile trays from the tray sterilising tunnel to the process Barrier/Isolator.

- Contained transfer systems (CTS), independently tested to below 5 nanograms offers ultimate safety, simplicity of operation and is easy to decontaminate.

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Telstar Life Sciences UK Ltd. is the centre of excellence for the Aseptic and Containment Barrier Isolation technology of Telstar. Aseptic Barrier Isolation is an ever more important part of any pharmaceutical process. A clear understanding of the process is challenges presented by clients’ individual requirements.

Telstar rises to demands in pharmaceutical Aseptic and Containment Barrier Isolation equipment, providing solutions for specific Recognised Leaders in Aseptic Technology

industry standards. Telstar is constantly adapting and addressing ever changing industry needs, evolving inline with regulatory authorities and industry needs, evolving inline with regulatory authorities and

on a day to day basis.

Telstar puts 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. Supported by continual investment in 3D software technology operated by design personnel from an engineering background, 3D design provides a clearer visualisation of the entire project preventing clashes, resulting in accurate production of 2D drawing elevations.

Telstar’s Life Sciences UK Ltd. is the centre of excellence for the Aseptic and Containment Barrier Isolation technology of Telstar. 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 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. Supported by continual investment in 3D software technology operated by design personnel from an engineering background, 3D design provides a clearer visualisation of the entire project preventing clashes, resulting in accurate production of 2D drawing elevations.

Identifying critical issues and preventing potentially costly problems before they occur.

Robotic Arm

Full mechanical and software integration of a robotic arm automates the transfer of empty trays from the entry door, places them on the X-Y-Z loading/unloading frame and fills them with liquid product for loading into the freeze dryer. The robotic arm is also employed to retrieve the trays containing the freeze-dried product from the X-Y-Z frame after unloading from the freeze dryer, placing them on the exit out feed conveyor for automated transfer to the vacuum transfer chamber.

Steriliser Interface

Aseptic interface with the tray sterilising tunnel, featuring an automated pneumatic door and tiltable seal.

Telstar provides complete systems, integrating high quality barrier systems with either Telstar process equipment or third party devices. Infrared sensors in the freeze drying process we are able to provide highly successful solutions implementing high efficiency cyclone vacuum devices coupled to BIC, post heat conical blending and BC filling. Automated weighing, sampling and filling systems provide end product pack-off to clients choice of container. Additionally Telstar barrier systems can be designed to provide aseptic barriers between the operator and other process equipment including fill/fitting boxes, capping machines, washing machines, autoclaves and sterilising tunnels.

Illustrations showcase Telstar’s global capability, which is achieved by close collaboration between Telstar’s global centres of excellence. The barrier systems expertise is proven by Telstar’s Life Science UK division located at Dewsbury in the UK.
Telstar Life Sciences UK Ltd, is the centre of excellence for the Aseptic and Containment Barrier technology of Telstar.

Aseptic Barrier Isolation is an ever more important part of any pharmaceutical process. A clear understanding of the process is paramount to its success.

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

Recognised Leaders in Aseptic Technology

Telstar meets to demands in pharmaceutical aseptic and containment barrier Isolation equipment, providing solutions for specific challenges presented by clients’ individual requirements.

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A leading pharmaceutical company report stated about 25% of all lost time illnesses were caused by ergonomically related issues. Telstar put great emphasis on the need to perform ergonomics trials, at the onset of all projects to identify issues and prevent them becoming a problem. Models together with trials serve to validate the process operations involved.

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Telstars hallmark at every stage:

- Exacting attention to detail and complete understanding of the process.
- Evaluating and understanding process equipment operations, container, ergonomic issues and integral ergonomic trials are critical elements to success.
- Identifying critical issues and preventing potentially costly problems before they occur.

Aseptic bulk product pack-off line

Bulk product contained in an IBC can be blended on a post hoist or dedicated conical blender prior to pack-off.

Final product is filled, crimped and sealed into aluminium kegs.

Telstar provides complete systems, integrating high quality barrier systems with either Telstar process equipment or third party devices.

If required Telstar’s systems can be designed to fully interface with Telstar or third party Lyophilisers, loading/unloading systems and robotic arms to fully automate processes, for example, liquid product tray filling prior to the freeze drying process.

To facilitate ideal product transfer and pack-off following the freeze-drying process we are able to provide highly successful solutions implementing high efficiency cyclic vacuum transfer systems coupled to IBC’s, post hoist/conical blending and IBC filling. Automated weighing, sampling and filling systems provide end product pack-off to clients’ choice of container.

Additionally Telstar barrier systems can be designed to provide aseptic barriers between the operator and other process equipment including vial filling lines, capping machines, washing machines, autoclaves and sterilising tunnels.

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Aseptic bulk product pack-off line

Vacuum transfer chamber

Operations work through gloves using a vacuum hose to sequentially move the freeze dried product from tray, via a high efficiency cyclic transfer system mounted on a frame above the IBC.

Robotic Arm

Full mechanical and software integration of a robotic arm automates the transfer of empty trays from the entry door, places them on the 4-IBC loading/unloading frame and fills them with liquid product for loading into the freeze dryer. The robotic arm is also employed to retrieve the trays containing the freeze dried product from the 4-IBC frame after unloading from the freeze dryer, placing them on the exit out feed conveyor for automated transfer to the vacuum transfer chamber.

Steriliser Interface

Aseptic interface with the tray sterilising tunnel, featuring an automated pneumatic door and sterilisable seal.

Telstar designs, supplies and installs custom barrier systems for an extensive range of sterile drug manufacture.

Telstar’s high quality systems provide the required internal aseptic environment for sterile powder manufacture, ensuring achievement of full European and FDA Approvals.

Telstar’s barrier systems are innovative and flexible accommodating all aspects of the manufacturing process. Telstar’s vast experience and capability to develop and manufacture these systems entirely in-house provides a cost-effective solution and assures quality control over the whole process.

Inclusion of CIP/BP systems and Biodecontamination generation/cycles, provide the required aseptic conditions. Humidity and temperature control is offered to maintain the internal environmental parameters.

Integration includes ergonomically proved mechanical interface supported by software controls and instrumentation via PLC platforms and HMI operator interface.

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Recognised Leaders in Aseptic Technology

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- Evaluating and understanding process equipment operations, container, ergonomic issues and integral ergonomic trials are critical elements to success.
- Identifying critical issues and preventing potentially costly problems before they occur.

Aseptic bulk product pack-off line

Bulk product contained in an IBC can be blended on a post hoist or dedicated conical/blender prior to pack-off.

Final product is filled, crimped and sealed into aluminium kegs.

Telstar provides complete systems, integrating high quality barrier systems with either Telstar process equipment or third party devices.

If required Telstar’s systems can be designed to fully interface with Telstar or third party Lyophilisers, loading/unloading systems and robotic arms to fully automate processes, for example, liquid product tray filling prior to the freeze drying process.

To facilitate ideal product transfer and pack-off following the freeze-drying process we are able to provide highly successful solutions implementing high efficiency cyclic vacuum transfer systems coupled to IBC’s, post hoist/conical blending and IBC filling. Automated weighing, sampling and filling systems provide end product pack-off to clients’ choice of container.

Additionally Telstar barrier systems can be designed to provide aseptic barriers between the operator and other process equipment including vial filling lines, capping machines, washing machines, autoclaves and sterilising tunnels.

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Aseptic bulk product pack-off line

Vacuum transfer chamber

Operations work through gloves using a vacuum hose to sequentially move the freeze dried product from tray, via a high efficiency cyclic transfer system mounted on a frame above the IBC.

Robotic Arm

Full mechanical and software integration of a robotic arm automates the transfer of empty trays from the entry door, places them on the 4-IBC loading/unloading frame and fills them with liquid product for loading into the freeze dryer. The robotic arm is also employed to retrieve the trays containing the freeze dried product from the 4-IBC frame after unloading from the freeze dryer, placing them on the exit out feed conveyor for automated transfer to the vacuum transfer chamber.

Steriliser Interface

Aseptic interface with the tray sterilising tunnel, featuring an automated pneumatic door and sterilisable seal.

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Inclusion of CIP/BP systems and Biodecontamination generation/cycles, provide the required aseptic conditions. Humidity and temperature control is offered to maintain the internal environmental parameters.

Integration includes ergonomically proved mechanical interface supported by software controls and instrumentation via PLC platforms and HMI operator interface.
Telstar Aseptic Barrier Systems are designed to provide solutions adhering to regulatory standards and guidelines. Running at positive pressure during normal conditions with auto change to negative in the unlikely event of system breech, when toxic products are involved.

Full consideration and design planning is applied to the product and equipment entry, and exit from the system to ensure the aseptic conditions are maintained throughout the process.

Mobile transfer systems/carts are available with dedicated air-handling capabilities. Providing a SOU aseptic environment the cart is complete with a shelf inducing arrangement for the holding, unloading and transfer of sterile trays from the tray sterilising tunnel to the process Barrier/Isolator.

The carts feature a connection port with an inflatable seal, docking takes place under the isolator and directional flow canopies to ensure aseptic conditions. The carts also feature connection and necessary valve arrangement to allow bio-decontamination via a hydrogen peroxide generator.

Telstar’s standard range of mobile transfer systems (CTS), independently tested to below 5 nanograms offers ultimate safety, simplicity of operation and is easy to decontaminate.

The filter can be used with a positive or negative bag in/ bag out grommet connection. The purpose of the port is to allow aseptic transfer of materials to and from the isolator or waste out of the isolator in a controlled manner, ensuring the integrity of the isolator internal environment remains intact at all times.

Telstar’s aseptic range of sterile test isolators are designed to accommodate the rising demand within the pharmaceutical industry and can be supplied with various industry standard decontamination gases according to choice.

Telstar also offers its own in house plasma charged bio-decontamination system, which was developed by Telstar for use in isolators, providing a unique cost effective alternative. For more information on this range please refer to Telstar’s dedicated brochure available for download from the website.

Fully Compliant

Telstar Aseptic Barrier Systems are guaranteed to comply with relevant standards and demands set by the regulatory bodies to ensure conformance and client satisfaction, including:

- ISO 14644-1 Cleanroom & Associated Controlled Environment
- US 2001 Airborne Particulates Classrooms
- cGMP Guidelines (current Good Manufacturing Practices)
- EPE guidelines (The Society of Pharmaceutical and Medical Device Professionals)
- FDA (Food and Drug Administration)
- A3C (Medical Control Agency)
- American Cleanrooms Society Guidelines

Telstar offers a comprehensive validation service to clients providing EU/GMP/ISO14644-1 Cleanroom & Associated Controlled Environment and has an in house specialists team to provide tailored solutions adhering to regulatory standards and guidelines. Running at positive pressure during normal conditions with auto change to negative in the unlikely event of system breech, when toxic products are involved.

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The carts feature a connection port with an inflatable seal, docking takes place under the isolator and directional flow canopies to ensure aseptic conditions. The carts also feature connection and necessary valve arrangement to allow bio-decontamination via a hydrogen peroxide generator.

Telstar’s aseptic range of sterile test isolators are designed to accommodate the rising demand within the pharmaceutical industry and can be supplied with various industry standard decontamination gases according to choice.

Telstar also offers its own in house plasma charged bio-decontamination system, which was developed by Telstar for use in isolators, providing a unique cost effective alternative. For more information on this range please refer to Telstar’s dedicated brochure available for download from the website.