

CREATING NEW VALUE

Steritainer Usage Cases

SEKISUI SEIKEI CO., LTD.

Powder drug substance adjustment in an isolator (Highly active medicine development department)



Current situation

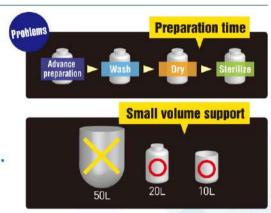
A small volume of a culture medium, buffer, or drug substance is stirred and adjusted by using a glass container and stainless steel tank.

Problems

- · Processes of washing and sterilizing containers and tanks are required.
- An appropriate-sized tank is not available (using a 50-liter stainless steel tank, for example, for creating a 10-liter culture media).
- For hard bottles, space for storing empty containers is required. It is difficult to use them in a small area such as an isolator.
- . Stirring is not possible for 2D bags; realization of Single Use has been given up.

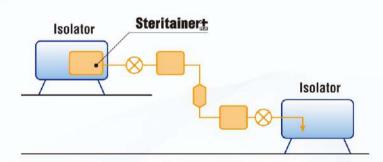
After

For Steritainer Plus, the container alone can stand on its own thanks to its 3D shape. Since the opening section is detachable, like a glass container, stirring and adjustment with a magnetic stirrer are possible.



Case for consideration

Adjusting a powder drug substance for injections with high pharmacological activity in an isolator





Case subject

Adjustment in a small space such as an isolator (Anticancer drug manufacturer, automated cell culture equipment manufacturer, etc.)



Current situation

After cultured in a stainless steel tank, cells are temporarily stored in 2D bags, and then transferred in liquid to the divided injection process by connecting a tube.

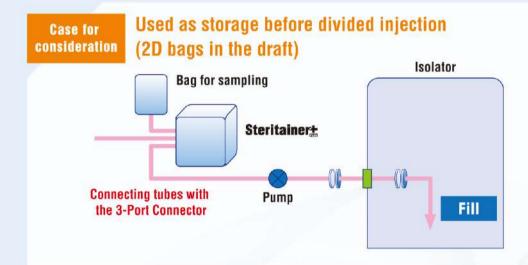
Problems

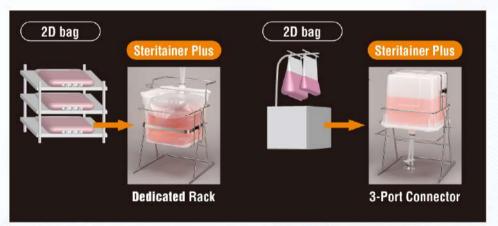
- The rack for mounting a 2D bag is big, making handling in a small space difficult.
- When lifting up a container for discharging liquid, lifting 20 litters is a large load.
- The outer box is large, and space for storing empty containers is also required.
- The cost of containers is large, and their delivery periods are not regular.

After

Space saving realized by putting Steritainer Plus into RIC and connecting tubes using a port connector







Case subject

Temporary storage of culture media before divided injection (Culture media manufacturer, etc.)

Transportation of drug substance to the outsourcing contractor (Low molecular medicine R&D department)



Current situation

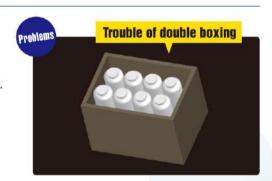
Since the drug substance is transported between sites, it is transported in double-boxed glass containers and as a refrigerated cargo.

Problems

- 2D bags cannot be transported, so there has been no alternative but to transport a drug substance in a container with glass containers filled with cushion material.
 An accident causing damage may occur depending on how the cargo is handled.
- . Since a large-capacity glass container is likely to break easily, the drug substance is divided into small containers.
- Sterilization using an autoclave in advance is necessary, and filling requires much work because containers need to be filled one by one manually.

After

Space saving realized by putting Steritainer Plus into RIC and connecting tubes using a port connector

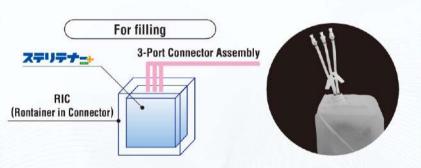


Case for consideration

Transporting a solid medicine drug substance to an outsourcing contractor as a refrigerated cargo (housed in a drum)







After being filled with the connector replaced with a cap, Steritainer Plus in RIC as-is is transported. Liquid is discharged on the outsourcing contractor side by mounting a connector with tubes that has been given in advance.

Case subject

Transportation in small volumes to an outsourcing contractor (Biomedicine development department, etc.)

Waste liquid storage bag in the purification process (Drug manufacturer research department)



Current situation

2D bags or hard bottles are used for waste liquid storage in the purification process and others.

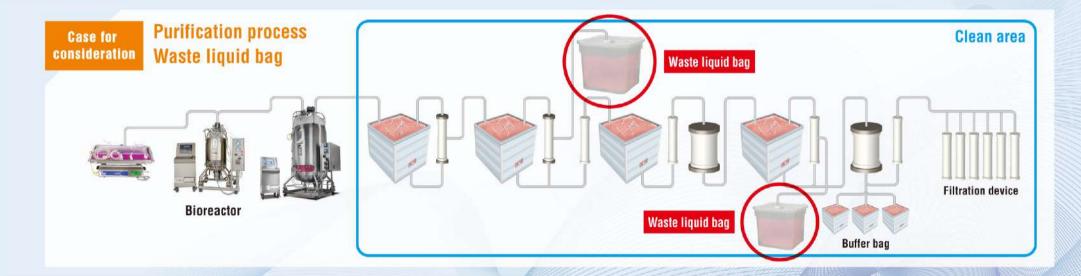
Problems

- For use in clean areas, already sterilized bags are required.
 Reason for the necessity of sterilized bags: Risk of contaminating clean areas.
 To eliminate the risk of contamination inside the equipment via connected tubes.
- Hard bottles must be sterilized using an autoclave in advance.
- 2D bags have a problem with installation space.

After

The use of Steritainer connected to tubes via the 3-Port Connector considered





Case subject

As a waste liquid storage container for a sterile room, CPC (Cell Processing Center), and others (Drug manufacturer, university CPC)



Current situation

Hard bottles are used as storage containers before divided injection into culture media bottles.

Problems

- . For hard bottles, person-hours are required for washing and sterilizing bottles.
- · Space for storing empty containers is required.
- The inside of the safety cabinet is small; it is not easy to work using hard bottles, which are rather high in size.
- · Hard bottles cannot be connected in a closed system.

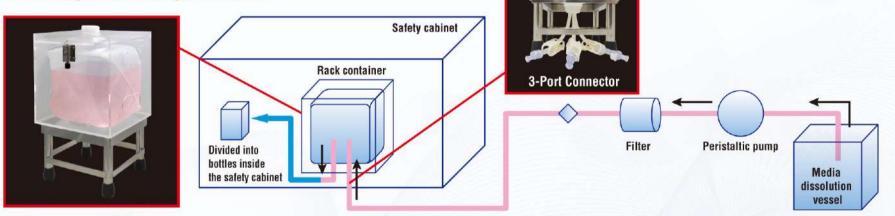
After

Space saving installation realized with Steritainer and optional acrylic case + rack. Closed-system connection is possible by using a tube set.



Case for consideration





Case subject

Use for dividing media and others into bottles (Regenerative medicine culture media manufacturer, etc.)

Supply of culture media to a WAVE bioreactor (Regenerative medicine research department)



Current situation

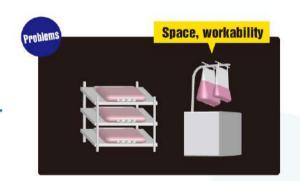
20-liter 2D bags are used for supplying media to a bioreactor.

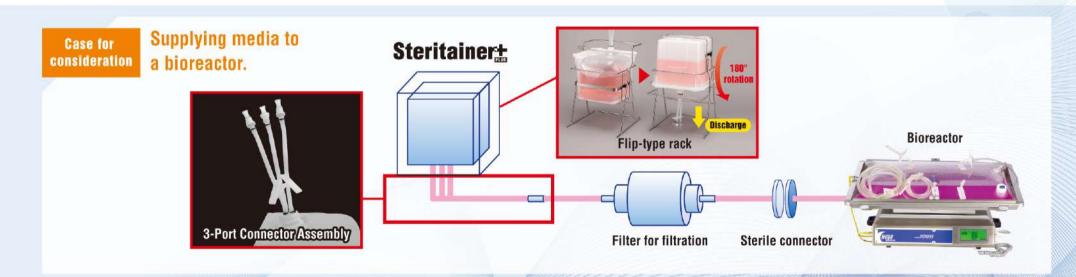
Problems

• In a small laboratory, installation space is required and handling is difficult.

After

- Space saving is realized with Steritainer Plus + flip-type rack (optional).
- 3-Port Connector assembly is used to realize the closed-system connection.





Case subject

User using a WAVE bioreactor





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