Disposable Technology: Validation of a Novel Disposable Connector for Sterile Fluid Transfer

One of the key challenges in disposable manufacturing is the integration of components and systems in a production environment while ensuring the safe and robust transfer of sterile fluid components. This is because existing technology is limited to aseptic connections that risk microbiological contamination of products resulting in costly and labor intensive solutions. A novel new connection device, the Lynx® S2S sterile to sterile connector, has been developed to address the need for a robust solution for sterile liquid transfer between two pre-sterilized (gamma) disposable components.

**LYNX S2S CONNECTORS**
The Lynx S2S connector comprises a male and female coupling set designed to facilitate the connection of two independently sealed fluid streams into a single, sterile fluid path. Both units of the connector utilize a hose barb fitting to connect desired bags, containers or assemblies. The Lynx S2S connector’s process contact materials are constructed of polycarbonate with an over-molded thermoplastic elastomer (TPE) gasket, allowing for gamma irradiation up to 45 kGy.

The male and female coupling sets of the Lynx S2S connector utilize solid plugs with O-ring seals and gaskets for containment. After the couplings have been gamma irradiated, the two sterilized assemblies can be connected by a series of simple steps in either a classified or non-classified environment. During the connection process, the plugs are isolated by moving them up and away from the fluid path in the female coupling body through the actuation process. This mechanism assures sterile fluid path and enables the liquid to flow through the connection in a contained environment. The S2S is a single use, single actuation device.

**LYNX VALIDATION STUDIES**
This connector has been subjected to rigorous microbiological validation studies to demonstrate its robust design and functionality. The results obtained clearly indicate that the connector provides a high degree of sterility assurance during a sterile fluid transfer process.

**AEROSOLIZED MICROBIAL CHALLENGE OF THE LYNX S2S**
Using a disposable glove bag as an isolator, the Lynx S2S device was challenged with a suspension of *Brevundimonas diminuta* at \( \geq 4.4 \times 10^6 \) cfu/mL. The suspension was aerosolized via an ultrasonic nozzle in the glove bag until the total bacterial count within the system was at least \( >10^6 \) cfu. The Lynx S2S connector was connected and actuated in this aerosolized environment, followed by a transfer of 500 mL sterile Tryptic Soy Broth (TSB) through the connector under constant bacterial aerosolization. The test flasks, negative (sterile TSB) and positive controls (TSB + *B. diminuta* culture) were incubated and observed for turbidity over a seven-day period. No growth was observed in the media test and negative control flasks.

**MICROBIAL CHALLENGE OF THE LYNX S2S PLUGS**
The solid plugs on the male and female couplings use an O-ring seal for containment before the connection is made. A total of 100 µL of \( 4.4 \times 10^7 \) *Brevundimonas diminuta* cells (50 µL on each plug) was inoculated around the perimeter and on the surface of each of the plugs depositing at least \( >10^6 \) cfu/mL. The Lynx S2S connector was connected and actuated, followed by a transfer of 500 mL of media through the connector. The negative and positive control flasks were incubated at 30 °C and observed for turbidity over a seven-day period. No growth was observed in the test and negative controls.

**CONCLUSION**
The design of the Lynx S2S connector has demonstrated a quality and robustness that will provide significant benefits to the industry by facilitating sterile transfer of fluids with a greater degree of security and safety. As part of Millipore Mobius™ flexible bioprocessing solution set, the Lynx S2S connector is an important component in ready-to-use disposable assemblies, and delivers safe and robust connections for various unit operations within the biopharmaceutical industry.

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