Quick Disconnect Aseptic Connection Study

Background

Quick disconnect connectors that can interrupt flow and provide a low leak / leak free seal have been available for some time. As these connectors migrate into the marketplace, the need for sterile connectors permitting aseptic connection is becoming more important to various industries requiring clean systems free of microorganisms that could affect the end output, safety or efficacy of the product being produced. Current connecting systems are capable of aseptic connections but require specialized geometries to achieve acceptable results at 7-day intervals.

SeriesLock was designed with sterility and aseptic connection in mind. With its Spring Free Flow Path™ and recessed mating features on both sides of the connection, connector sterilization and aseptic connections are made possible using its standard product line offering.

Methods

Various tests were performed to determine the ability of the SeriesLock Quick Disconnect Fitting to sterilize and remain sterile by itself and when connected. Test methods were first established to define the testing and the microorganism detection methodologies to represent real-world scenarios. SeriesLock connectors with PVDF housings were utilized for this testing as they allow for steam sterilization which represents the worst-case scenario out of all sterilization methods (verses radiation and EtO processing).

Once sterilization was achieved, microbial ingress testing was performed in two main configurations, (1) connectors with attached tubes to simulate prepared sterile lines and connectors prior to connection and (2) with connected systems permitting flow from the female to male side of the assembly. For the connected systems approach, the connection was always performed with pre-sterile female and male connector assembly halves, but the connection method varied to replicate all possible real-world scenarios.

The first connection was in-air with no additional microbial contamination introduced. The second connection method was to dip each sterilized half of the connector assembly in a bacterial inoculum consisting of Staphylococcus aureus (S. aureas) since it is commonly associated with human skin and would be the most applicable source of contamination should it occur. The connected assembly was then removed from the inoculum and dried for one hour prior to connecting. The third connection method was to dip both female and male assemblies into the inoculum and complete the connection. The connected assembly was then removed from the inoculum.

All test samples exposed to inoculum during the connection process, i.e. dipped and submerged;

1. utilized *S. aureas* (ATCC 6538) inoculum,
2. were swabbed and serially diluted and plated in Tryptone Soya Agar (TSA) and Mannitol Salt Agar (MSA) which is a medium specific for the detection of *S aureus*, to determine initial microbial levels,

3. were incubated at 31°C for 14 days, and
4. were assessed for sterility (turbidity) using the TSA method with plates incubated at 31°C for 5 days.

Additionally, control samples were prepared consisting of;

1. Positive Control – inoculation of a sterile connector assembly with a known level of S aureus (74cfu).
2. Negative Control 1 – unconnected female and male connector assemblies re-incubated for 14 days, and
3. Negative Control 2 – assemblies connected in the submerged configuration and then re-incubated for 14 days.

Results

1. All control samples performed as expected.
   1.1. Positive control testing determined the inoculum level to be 74cfu of S aureus. Growth of S aureus was determined within the assemblies.
   1.2. Negative controls, both re-incubated for 14 days and assembled submerged / re-incubated for 14 days, remained sterile with no microbial growth observed.
2. With respect to the three connection methods:

Connection Type	Determined Inoculum Level	7 Day Result
In Air	Female Connector $7.4x10^2$ cfu Male Connector $3.8x10^4$ cfu	5/5 PASS
Dipped	Female Connector $1.4x10^8$ cfu Male Connector $9.2x10^7$ cfu	4/4 PASS
Submerged	Suspension $3.8x10^8$ cfu/mL	4/4 PASS

3. All connection types at 7-day time intervals passed the connection study requirements maintaining that the female/male connector pairs demonstrated the ability to maintain sterility in both the pre-connected and connected states.
4. All non-connected female and male assemblies maintained sterility for 14 days (prior to connection).