



RE: MicroCLAVE® Neutral Displacement Connector Microbial Challenge Interpretation

Thank you for your interest in the MicroCLAVE Neutral Connector. MicroCLAVE is constructed from the original CLAVE *dedicated internal fluid path technology* and actually shares the overall design of the CLAVE and silicone sealing component of the CLAVE itself. The shared design attributes and components are what make-up the microbiological barrier of the MicroCLAVE and therefore share the studied history of the CLAVE.

This letter describes the attributes of the CLAVE's microbiological barrier to bacteria according to the paper ***Extended use Microbial Challenge and Disinfection Study of the CLAVE Connector***. What this paper demonstrates is that in NO instance did the challenge organism violate the physical barrier and enter the fluid path. In addition, the CLAVE which has been commercially available since 1993 has never been associated with a reported nosocomial infectious event.

The MicroCLAVE Connector is designed to accept multiple accesses from a standard male luer and maintain a physical barrier to bacteria. The functional design is such that the male luer depresses the silicone seal over the internal spike, which in turn accesses the fluid path. From testing we can determine that that MicroCLAVE may be accessed at least 144 times where it is proven to maintain its physical barrier properties. Please visit our website at <http://www.icumed.com/micro-clave-connector.asp> to view an animated video which describes the CLAVE's unique internal fluid path.

The MicroCLAVE is able to accomplish this in three ways.

1. The silicone seal upon which the male luer makes contact for access is a swab-able surface, or *physical barrier* to bacteria. This was demonstrated in the study by when the product was inoculated with an average of 870 colony forming units of *Pseudomonas Aeruginosa* and then swabbed using and "*aggressive circular motion for three seconds*". This swab was done with *70% isopropyl alcohol*. The test results show no evidence of microorganisms entering the fluid path. In other words, the function of swabbing effectively removes all bacteria and creates a sterile entry point. It also demonstrates that the internal components of the MicroCLAVE and fluid path remained sterile.
2. The silicone seal of the MicroCLAVE Connector is a *compression seal*, capable of maintaining 60psig backpressure. The seal in its resting or inactivated state also prevents the ingress of microorganisms as demonstrated in the study.
3. The contact between the male luer and the silicone seal of the MicroCLAVE, which occurs when the male luer accesses the MicroCLAVE, is also that of a *compression seal* capable of closing the fluid path to outside contaminants. When accessed, no external surfaces of the luer or MicroCLAVE are in contact with the fluid path.

Thank you again for your interest, for further questions or concerns, please contact our corporate offices at 949-366-2183 or 800-824-7890.

Technical Services
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