



RE: CLAVE® Needlefree Connector Disinfection Recommendation

Thank you for your interest in the CLAVE Connector and recommendations for swabbing procedures. According to the CLAVE directions for use, the split-septum seal should be *swabbed before each use in accordance with validated facility protocol*. What this means is that the CLAVE should be swabbed in accordance with the current established protocol unique to the facility using the CLAVE.

ICU Medical has evaluated the CLAVE's ability to be effectively disinfected and to prevent microbial ingress in the *Evaluation of the CLAVE® Technology and Resistance to Microbial Ingress* report available on the ICU website. This study follows a pre-determined swab procedure which is described as an *"aggressive circular motion for three seconds"*. This swab was done with *70% isopropyl alcohol*. The results of this study demonstrate that if you use this technique, the injection site of the CLAVE will be sterile each and every time you access. In order to be compliant with FDA laws, ICU representatives will work with an individual facility to ensure that proper education of that particular facility's protocol and how they interact specifically with the CLAVE are communicated.

The CLAVE is chemically compatible with Isopropyl Alcohol, Betadine and Chlorhexadine disinfectants. This includes antibacterial cap devices that may be used as well. However, some of these disinfectants such as Chlorhexadine leave residuals on the device which can crystallize. These residuals will not interfere with the CLAVE function, and can be routinely removed using a standard isopropyl swab.

Thank you again for your interest, if there are further questions or concerns please visit our website at www.icumed.com, or contact the corporate offices at 949-366-2183 or 800-824-7890.

Technical Services
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