



**RE: CLAVE® NeedleFree Connector Change Protocol**

Thank you for your interest in the CLAVE Connector and recommendations for change procedures. As a U.S. Medical Device Manufacturer regulated by NSAI and ISO13485; the U.S. Food and Drug Administration (FDA) prohibits ICU from recommending specific clinical practice regarding any medical procedure which is ultimately the responsibility of the health care provider such as change protocol. According to the CLAVE directions for use, the device should be *changed in accordance with CDC Guidelines or validated facility protocol*. What this means is that the CLAVE should be changed in accordance with the current established protocol for infusion therapy devices in the facility.

The intent of this requirement by the FDA is to ensure that a device is compatible and does not limit a facility to a specific protocol which may contradict an already established protocol in that facility. This is why a specific change protocol is not appropriate or legal on the device label.

What ICU Medical does offer it's users is what we know to be the most common practices for the CLAVE which have been proven safe and effective for most users. The most common change protocol is at 72 hours and in conjunction with the standard tubing change protocol for the facility. We are aware that some users are converting to a 96 hour change protocol which the CLAVE also supports. In the alternate care setting we recognize that some users will change the CLAVE on PICC catheters once per week in conjunction with the dressing change. The CLAVE is also compatible with blood products and may be used for both blood sampling and infusion without requiring a change procedure. When using blood products with the CLAVE the post flush procedure should be carefully considered to ensure that blood residue has been appropriately flushed. Please refer to our white paper *CLAVE Connector Blood Compatibility Studies*. The CLAVE has been validated for functional integrity specific to these common protocols and ICU is aware of many users worldwide successfully employing these practices.

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

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