



RE: Administration, Aspiration and Flushing of Blood and Blood Components through MicroCLAVE[®]

Thank you for your interest in the MicroCLAVE by ICU Medical, Inc. The MicroCLAVE is a hybrid technology of the original CLAVE[®] Connector which includes a copy of the internal fluid path and seal, held together by a streamlined housing. The housing has no role in the fluid path and therefore CLAVE studies are appropriate models for consideration of the MicroCLAVE performance.

Various studies have been performed to validate the use of the CLAVE technology in blood applications. Studies include an administration and aspiration study to demonstrate that no significant hemolysis occurs, and a flush analysis which demonstrates that following the travel of blood through the device, the CLAVE can be flushed clean. Following are the specified reports which have evaluate these attributes.

1. SE20-00264. Hemolysis Study of the CLAVE.
2. SE60-00009. CLAVE Flow Rate and Flush Analysis Using Whole Citrated Bovine Blood.
3. Hemolysis Blood Draw Study for the CLAVE.

The studies verify that blood and blood components may be safely infused and aspirated through the MicroCLAVE without the risk or hemolysis. The flush study also demonstrates that the MicroCLAVE can be effectively flushed and cleaned of blood products after use due to the straight through fluid path which offers no crevices for blood to remain. Additionally, the slightly reduced deadspace in the MicroCLAVE (0.04cc) vs. the standard CLAVE (0.06cc) reduces further the volume of flush required. We recommend flushing the MicroCLAVE after each use with normal saline or in accordance with facility protocols. Flush volumes for volume restricted patients such as in the NICU should continue to follow current hospital protocols.

ICU Medical recommends that the MicroCLAVE be changed in accordance with validated facility protocols. The intent of the studies completed by ICU Medical is to provide guidance for the Healthcare Provider in determining what appropriate use protocols should be. ICU is aware that the majority of facilities using MicroCLAVE regularly administer or aspirate blood through the device and do not change it after such use. The MicroCLAVE has also been used in Bone Marrow Transplant and Stem Cell Transplant procedures in medical facilities including Children's Hospitals.

Furthermore, the MicroCLAVE device when used in conjunction with a blood bag spike for blood products would also be acceptable. The MicroCLAVE flow rate is better than an 18 Gauge needle and would represent the smallest orifice of which the blood product must pass through when used with a Blood bag spike.

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

Technical Services
ICU Medical, Inc.