



RE: Administration and Aspiration of Blood and Blood Components through the CLAVE® Connector.

Thank you for your interest in the CLAVE by ICU Medical, Inc. Various studies have been performed to validate the use of the CLAVE including 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 CLAVE without the risk or hemolysis. The flush study also demonstrates that the CLAVE can be effectively flushed and cleaned of blood products after use.

ICU Medical recommends that the CLAVE be changed in accordance with validated facility protocols. We also recommend flushing the CLAVE after each use with normal saline or in accordance with 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 Medical is aware that the majority of facilities using CLAVE, regularly administer or aspirate blood through the device and do not change it after such use. The CLAVE has also been used in Bone Marrow Transplant and Stem Cell Transplant procedures in medical facilities including Children's Hospitals.

Furthermore, the CLAVE device when used in conjunction with a blood bag spike for blood products would also be acceptable. The CLAVE 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 visit our website at www.icumed.com or contact our corporate offices at 800-824-7890 or 949-366-2183.

Technical Services
ICU Medical, Inc.