



RE: MicroCLAVE® Compared to the Standard CLAVE® Connector

Thank you for your interest in the ICU Medical MicroCLAVE. The MicroCLAVE is a new concept product which utilizes tested and tried performance attributes of the original CLAVE Connector in a new low profile design. The purpose of the MicroCLAVE is to provide a smaller, more streamlined product which may be more comfortable to the patient against the skin than the original CLAVE Connector. The only functional difference between the MicroCLAVE and the original CLAVE is that the MicroCLAVE has a slightly lower deadspace of 0.04cc, making it particularly appropriate for pediatrics and volume restricted patients. This difference results from a slightly shorter overall length of the male luer component and does not affect any other performance characteristics. The following table demonstrates the comparative functional attributes of the two products:

Function	MicroCLAVE	CLAVE
Flow Rate	> 18 gauge	> 18 gauge
Deadspace	0.04cc	0.06cc
Backpressure	> 45 psig	> 45 psig
Lipid compatible	Yes	Yes
Chemo compatible	Yes	Yes

Microbiological Barrier:

The MicroCLAVE utilizes the same sealing components and geometry which are used in the original CLAVE and therefore enjoys the same protective qualities and reliability of the CLAVE. These components have undergone a variety of microbiological challenges under the CLAVE name for which the results are equally applicable to the MicroCLAVE. All testing revealed zero contamination of the fluid path following a repeated use simulation.

- Extended Use Microbial Challenge for CLAVE Connector: Test Report SE20-00226 January 1998. Challenge Organism: *Pseudomonas aeruginosa*.
- Extended Use Microbial Challenge for CLAVE Connector: Test Report SE00-75t September 2000. Challenge Organism: *Staphylococcus epidermidis*.

Use with Blood Products:

In the same way that the MicroCLAVE enjoys the CLAVE characteristics as a microbiological barrier, it also enjoys equal performance for use with blood products. The following test reports are applicable to both CLAVE and MicroCLAVE.

- Test Report SE20-00264 April 1998. Hemolysis Study of the CLAVE Connector.
- Test Report SE60-00009 November 1997. CLAVE Flow Rate and Flush Analysis Using Whole Citrated Bovine Blood.
- Test Report 01-040T August 2001. Hemolysis Blood Draw Study for the CLAVE.