

The CLAVE[®] Connector

Performance with High Risk Infusates

Introduction

It has come to the attention of **ICU Medical, Inc.** that some infusates, used in high risk clinical applications, can cause a plastic device such as the CLAVE Connector to degrade and not function as intended. The CLAVE Connector is designed to be a universal connector, capable of withstanding such infusates in order to qualify it for most clinical applications. This study is used to demonstrate the functional integrity of the CLAVE Connector when used with certain infusates that are known to be incompatible with plastics. The CLAVE Connector is manufactured using polycarbonate, polyester and silicone components. Five different drugs were used to conduct this study as follows: Taxol, Cisplatin, Adriamycin, Oncovin and Lasix.

Procedure

Sixty samples of the CLAVE Connector were assembled together as one test setup. The test infusate was prepared per the manufacturer's instructions and available in a 5cc luer lock syringe. Water available in a 5cc syringe was used as the study control. The syringe containing the test infusate was attached to the proximal end, or the silicone seal of the test setup, by fully activating the CLAVE Connector and securing the luer lock connection. The contents of the syringe was infused through the entire string of connectors until an excess of the drug was captured in a secondary syringe. The capture syringe was attached using a double female connector at the distal end or male luer of the CLAVE Connector test setup. The entire setup was a closed system and was monitored for leakage at any of the connection points. At one hour intervals the samples were tested for patency by pushing at the proximal syringe, and then reversing the action by pushing at the distal syringe. This action was repeated twenty four (24) times per day, for seventy two (72) hours or three days. At all times each of the CLAVE Connectors was exposed to the test infusate and the patency test. Following the three days of exposure the test infusate was disposed of per the manufacturer's instructions and the samples were generously flushed to remove any drug residue.

The samples then underwent functional and visual evaluation according to the CLAVE Connector's performance specifications. Flow testing was used to identify any degradation of the internal polycarbonate spike component. Backpressure testing to 60 psig was used to identify any degradation of the silicone seal and polyester housing. All samples were visually inspected for degradation. The results of the study are reported in the following table:

Results

Test Infusate	Flow Rate: number of failures per 60 samples	Backpressure: number of failures per 60 samples	Overall Failure Rate for Test Infusate
Taxol (2mg/mL):	0/60	0/60	0%
Cisplatin (2mg/mL):	0/60	0/60	0%
Adriamycin (3mg/mL):	0/60	0/60	0%
Oncovin (1mg/mL):	0/60	0/60	0%
Lasix (100mg/mL):	0/60	0/60	0%
Control Water:	0/60	0/60	0%

Conclusions

The CLAVE Connector met its functional specifications following exposure to the test infusate. According to this study the CLAVE Connector should not suffer from any degradation when used with Taxol, Cisplatin, Adriamycin, Oncovin and Lasix.

CAUTIONS: Federal (USA) law restricts this device to sale by or on the order of a physician.
It is recommended this device be changed per CDC guidelines or per validated facility protocol

US. PAT. NOS; 5,685,866; 5,690,612; 5,694,686; 5,695,466; 5,873,862; 5,901,942; 5,928,204; 6,132,403;
6,572,592; 6,599,273; 5,738,663; 6,019,748; 6,325,782; 5,700,248; 6,132,404; 6,669,673; 6,635,044; 6,572,592;
6,682,509; 6,726,672 Other Patents Pending