

The Clave[®] connector: meeting functional specifications when exposed to high-risk infusates over a 72-hour period

PURPOSE

Some infusates used in high-risk clinical applications are known to be incompatible with plastics; they may cause degradation and device failure. The Clave connector is manufactured using polycarbonate, polyester, and silicone components and is designed to withstand damage by such infusates. This study was conducted to demonstrate the functional integrity of the Clave connector when used with Taxol, Cisplatin, Adriamycin, Oncovin, and Lasix.

MATERIALS AND METHODS

Sixty samples of Clave connectors were connected in one closed-test apparatus. Each drug infusate was prepared in five separate 5 cc luer lock syringes and was attached in turn to the proximal end of the test setup. The contents of each syringe were infused through each connector until excess was collected by a capture syringe attached with a double female connector at the distal male luer end of the test setup. During testing, the entire system was monitored for leaks at all connection points.

Over a 72-hour period, the samples were tested for patency at one hour intervals by first pushing at the proximal syringe and then reversing the action and pushing at the distal syringe. All of the Clave connectors were continuously exposed to the test infusates and the patency tests. After 72 hours of exposure, the test infusate was disposed of per manufacturers' instructions and the samples were generously flushed to remove any drug residue. Samples underwent functional and visual evaluation per product performance specification. Flow testing was conducted to identify degradation in the internal polycarbonate spike component. Backpressure testing to 60 PSIG was used to identify degradation of the silicone seal and polyester housing.

TABLE

Test Infusate	Concentration	Flow Rate: # of Failures per 60 Samples	Backpressure: # of Failures per 60 Samples	Overall Failure Rate for Test Infusates
Taxol	2 mg/mL	0/60	0/60	0%
Cisplatin	2 mg/mL	0/60	0/60	0%
Adriamycin	3 mg/mL	0/60	0/60	0%
Oncovin	1 mg/mL	0/60	0/60	0%
Lasix	100 mg/mL	0/60	0/60	0%
Control H ₂ O		0/60	0/60	0%

CONCLUSION

The Clave connector is designed to withstand most infusates so that it may be used in most clinical applications. In this study, the Clave connector met its functional specifications following 72 hours of exposure to the five test infusates. According to this study, the Clave connector should not suffer from any degradation when used with Taxol, Cisplatin, Adriamycin, Oncovin, or Lasix.