

Preventing Rupture of Vascular Access Devices during Procedures requiring Pressure

Introduction

The FDA has received hundreds of adverse event reports regarding ruptured vascular access devices during procedures requiring pressure, prompting them to issue warnings regarding administration under pressure. Ruptured devices may leak or spray fluids with the potential to cause harm to both clinicians and patients. To help prevent the rupture of vascular access devices the FDA has recommended that clinicians only use devices labeled with maximum pressure and flow rate.

Objective

To evaluate the performance of the Maximus Pressure Rated I.V. Extension Sets and another brand of extension sets labeled as compatible for use at 325 PSI, these sets were subjected to testing under simulated clinical conditions.

Testing Protocol

Two consecutive tests were performed. All test samples were preconditioned to simulate expected clinical use prior to the procedure. Pressure testing was performed by simulating pressurized delivery of a high viscosity fluid through the test samples capped with a 20 ga. peripheral catheter. A glycerin mix with a viscosity of 14.3 cps warmed to a temperature of $99 \pm 1^\circ\text{F}$ was delivered through each sample at a pressure of 325 psi, generating flow rates in excess of 10 ml/sec to simulate worst case scenario clinical conditions. During the test, extension sets were inspected for leakage. If leakage was observed, the location of the failure was recorded. Samples that passed the 325 PSI testing were then subjected to the same test procedure at 400 PSI, to simulate a potentially unsafe use of the 325 PSI rated extension set. Thirty five samples each of the Maximus Pressure Rated Extension Set and the other brand labeled for use to 325 PSI were tested.

Results

No failures of the Maximus Pressure Rated Extension Sets were observed during testing. The thirty five Maximus Pressure Rated Extension Sets tested experienced no leakage or bursting at 325 PSI and 400 PSI during simulated clinical use. This testing confirms that the Maximus pressure rated extension sets withstand pressures of 325 PSI and are thus safe to use during procedures requiring pressure up to 325 PSI. Fluid flow rates measured during this testing for both the standard bore and mini bore extension sets were greater than 10 mL per second, supporting a flow rate specification of 10 mL per second.]

In testing of the other brand of pressure rated extension sets at 325 PSI, twenty one extension sets failed at 325 PSI or less, a 60% failure rate. Of the remaining extension sets which did not fail at 325 PSI, all fourteen failed at pressure levels between 350 and 400 PSI. Failures of this brand resulted from tubing which burst during the simulated procedure. All thirty five samples of this brand failed, a failure rate of 100%.

Clinical Implication

Intravenous devices labeled for use under pressure must withstand the pressurized fluid flow expected during a typical procedure requiring pressure. Otherwise, adverse events such as device ruptures will continue to occur, with the potential for serious patient complications. To ensure devices perform adequately during clinical use, pressure rated extension sets should be tested for proper operation under simulated clinical conditions. Maximus Pressure Rated I.V. Extension Sets are proven to perform without failure at 325 PSI when tested under simulated clinical conditions. An important safety precaution facilities can implement is to use devices with proven performance. This is particularly critical when using vascular access devices under pressure. With Maximus Pressure Rated I.V. Extension Sets, clinicians can be confident that the devices will function as required, reducing the risk of adverse events related to these procedures.

