

Eliminating the need for I.V. Extension Set replacement during administration requiring pressure

A cost saving, easily implemented method of compliance with FDA recommendations for avoiding rupture and leaking of vascular access devices during procedures requiring pressure

The Problem: Rupturing of Vascular Access Devices during Infusions requiring Pressure

Advanced technology has provided medical professionals with procedures which serve as valuable tools in the diagnosis of certain conditions and disease states. Some of these procedures require the administration of fluids at elevated volumes over a short period of time, which increases the level of pressure exerted on the devices utilized, such as intravenous (I.V.) extension sets. While these procedures deliver clinically superior results, the peak pressure produced during these procedures can exceed the pressure tolerance of conventional I.V. extension sets, and this excess pressure can lead to the rupturing of the conventional extension set. Failure of the I.V. set during administration can lead to serious complications for the patient. A contributing factor to the continued occurrence of I.V. extension set rupture is the failure to replace a conventional I.V. set already in use on the patient with a specialized pressure rated set. Although the FDA has issued warnings, reminders and recommendations to help healthcare facilities reduce these events, and medical device manufacturers have developed pressure rated vascular access devices, failures of conventional I.V. extension sets continue to occur.

FDA Recommendations

The FDA has received hundreds of adverse event reports regarding ruptured vascular access devices during procedures requiring pressure, prompting them to issue warnings regarding proper use of devices during these procedures. To help prevent the rupture of vascular access devices, the FDA has issued several recommendations, including the following:

1. Check the labeling of each vascular access device for its maximum pressure and flow rate. If none is provided, assume the device is not to be used for this application.
2. Ensure that the pressure attained during the procedure does not exceed the maximum labeled pressure for the vascular access device.
3. Be aware the pressure required depends on many factors including flow rate, fluid viscosity, tube diameter and length and any obstruction to flow from kinks, curves and compression. Ruptures occur when the pressure exceeds the tolerance of the vascular access devices such as catheters, ports and extension tubing.

Practical Solution – An Innovative Pressure Rated I.V. Extension Set

The solution to this problem is a universal I.V. extension set which can be cost effectively utilized for both standard procedures and procedures requiring pressure. While there are a small number of pressure rated I.V. extension sets available, their prohibitive cost makes it unfeasible to use during every I.V. procedure, thus necessitating the change when pressure rated devices are required. Maximus has developed pressure rated I.V. extension sets economically comparable to conventional extension sets, thus this new device can be cost effectively utilized during all I.V. requirements, including procedures most effectively performed under pressure.

When the Maximus® Pressure Rated I.V. Extension Sets are used as a standard extension set, the additional cost required in replacing the conventional I.V. set with a pressure rated I.V. set is eliminated. Additional time and effort required from healthcare practitioners to change the I.V. sets before and after procedures requiring pressure is also eliminated. Using one universal I.V. extension set throughout treatment will aid in decreasing vascular access device failures during procedures requiring pressure, reducing patient discomfort and complications during these procedures.

Objective

The following study was conducted to validate that the MaxPlus® and Maximus Pressure Rated Extension Sets will function as intended and maintain structural integrity under situations of higher than normal pressure. In order to meet requirements for pressurized infusion, both the MaxPlus Positive Displacement Needleless IV Connector and the Maximus Pressure Rated I.V. Extension Sets were tested to withstand pressures up to 325 PSI.

Methods

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 Standard Bore Pressure Rated Extension Set and the Maximus Mini Bore Pressure Rated Extension Set were tested. None of the sets failed this pressure testing. Fluid flow rates measured during this testing for both the standard bore and mini bore extension sets were greater than 10 mL per second, leading to a flow rate specification for the Maximus Pressure Rated I.V. Extension Sets of 10 mL per second.

Results

This testing demonstrates that the MaxPlus Positive Displacement IV Connector and the Maximus Pressure Rated I.V. Extension Sets will withstand clinical situations where pressurized infusion up to 325 PSI may be indicated. The data collected and observations made during testing verify that the system will maintain its integrity and performance characteristics up to 325 PSI.

Clinical Implications:

Maximus Pressure Rated I.V. Extension Sets will enable healthcare facilities to reduce the risk of patient and healthcare worker exposure blood and other fluids due to ruptured vascular access devices improperly used during procedures requiring pressure. In addition, when Maximus Pressure Rated I.V. Extension Sets are utilized as the standard of care throughout the healthcare facility, costs normally associated with the purchase of specialized high pressure sets and placement of these sets prior to procedures requiring pressure will be significantly reduced. Eliminating the need to change the I.V. extension set before and after procedures will reduce time required to perform these procedures. Finally, cost of adverse events associated with failed vascular access devices will be greatly reduced. Maximus Pressure Rated I.V. Extension Sets allow the medical facility to easily and cost effectively comply with FDA recommendations, increasing safety for the patient and healthcare practitioner and enhancing the quality of patient care.

Selected References

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