Reducing the need for IV 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 (IV) extension sets. The peak pressure produced during these procedures can exceed the pressure tolerance of conventional IV extension sets, and this excess pressure can lead to the rupturing of the conventional extension set. Failure of the IV set during administration can lead to serious complications for the patient. A contributing factor to the continued occurrence of IV extension set rupture is the failure to replace a conventional IV 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 IV 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 IV extension set

The solution to this problem is a universal IV 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 IV extension sets that are available, their prohibitive cost makes it unfeasible to use during every IV procedure, thus necessitating the change when pressure rated devices are required. CareFusion has developed pressure rated IV extension sets economically comparable to conventional extension sets, thus this device can be cost
effectively utilized during all IV requirements, including procedures performed under pressure.

When the MaxPlus® pressure rated IV extension sets are used as a standard extension set, the additional cost required in replacing the conventional IV set with a pressure rated IV set is reduced. Additional time and effort required from healthcare practitioners to change the IV sets before and after procedures requiring pressure is also reduced. Using one universal IV 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 connector and MaxPlus pressure rated extension IV 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 needleless connector and the MaxPlus pressure rated IV extension sets were tested to withstand pressures up to 325 PSI.

**Methods**

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 20G peripheral catheter. A glycerin mix with a viscosity of 14.3 cps warmed to a temperature of 99º ± 1º F was delivered through each sample at a pressure of 325 PSI, generating flow rates in excess of 10 mL per second 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. Thirty five samples each of the MaxPlus standard bore pressure rated IV extension set and the MaxPlus minibore 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 minibore extension sets were greater than 10 mL per second, leading to a specification for the MaxPlus pressure rated IV extension sets of 325 PSI at a flow rate of 10 mL per second.

**Results**

This testing demonstrates that the MaxPlus needleless connector and the MaxPlus pressure rated IV 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**

Additional costs associated with the purchase of specialized high pressure sets and placement of these sets prior to procedures requiring pressure may be significantly reduced when MaxPlus pressure rated IV extension sets are utilized as a cost-effective standard of care throughout the healthcare facility. MaxPlus pressure rated IV extension sets allow the medical facility to easily and cost effectively comply with FDA recommendations.

References


Data on file at CareFusion.

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