Nuitiv™ Clear Needlefree Connector Drug and Chemical Compatibility

Report of a study commissioned by ICU Medical Inc. and conducted by DDL, Inc.

Background

The primary purpose of intravenous (IV) lines is to deliver fluid directly into the patient's bloodstream. This fluid can be comprised of saline and various other chemicals. Many of the IV line components, such as the inner lining of the IV set, pump cassette, needlefree connectors, and luers, have direct contact with the fluid path.

Material compatibility refers to a material's resistance to corrosion when it comes in contact with a chemical. As such, the compatibility of the IV line with commonly used chemicals is important because IV lines deliver fluid via pressure, where unexpected changes in pressure can change the rate of drug delivery. Testing pressure integrity is one way to evaluate the functional compatibility of an IV line with various chemicals; if a component is incompatible with a chemical, pressure leaks will occur.

Introduction

The purpose of this study was to evaluate the functional performance of the Nuitiv Clear needlefree connector after exposure to commonly used chemicals and to determine whether the Nuitiv Clear needlefree connector met the requirements for chemical resistance. Three tests were used to evaluate the functional performance of the PlumSet™ with the Nuitiv Clear connector: the pressure leak test, the vacuum leak test, and the pressure leak at 20 psi test.

Methods

Materials

Six chemicals were chosen for this study:

1. THAM (electrolyte)
2. Lipid emulsion (caloric agent)/propofol (anesthesia)
3. Busulfan (chemo)
4. Paclitaxel (chemo)
5. Etoposide (chemo)
6. Amiodarone (cardiovascular)

Chemical selection was based on chemicals or drugs commonly used with Nuitiv Clear needlefree connectors, specifically those with a medium to high risk of chemical interaction with materials in the Nuitiv Clear needlefree connector (i.e., copolyester and polycarbonate). Chemicals tested typically represent some of the most aggressive constituents of the representative drugs, which demonstrate Nuitiv Clear sets are lipid and chemotherapy compatible.

Nuitiv Clear samples consisted of 3-year-aged and unaged samples, specifically Lifeshield latex-free primary IV PlumSets with Nuitiv Clear connectors. All samples were sterilized at a range of 32-42 kGy using gamma sterilization.

Chemical Exposure/Conditioning

Each sample was completely filled through the Nuitiv Clear connector on the cassette with a chemical and exposed for the specified amount of time in Table 1 below. At the completion of exposure duration, each sample was purged with saline.

Table 1: Corner Case and Chemical Exposure Summary

List Number	Tham	Lipid Emulsion/ Propofol	Busulfan	Paclitaxel	Etoposide	Amiodarone
Exposure Duration	96 hours	24 hours	24 hours	24 hours	24 hours	96 hours
Replicate	n=45	n=45	n=45	n=45	n=45	n=45

Pressure Leak Test Method

For this test, samples were occluded subjected to pressure while submerged in water to test for leakage (i.e., steam of air bubbles). Specifically, chemically conditioned samples were obtained and checked for any occlusions that could prevent the flow of air pressure. The diaphragm of the cassettes was then occluded, and the flow regulators were set to the fully opened position. A pressure gauge was attached to the piercing pin side of the set. The set was immersed in a 40°C water bath and was subjected to an internal air pressure of 7.25 psig for a minimum of 15 seconds for observation.

Acceptance criteria for the pressure leak test is for no evidence of leakage (i.e., steam of air bubbles) using 7.25 psig, 40 +/- 1°C and holding for a minimum of 15 seconds during observation as per ISO 8536-1 A.3.2.

Vacuum Leak Test Method

For this test, the setup in Figure 1 below was used, where 10 samples were placed between two stopcock manifold assemblies and two flasks.

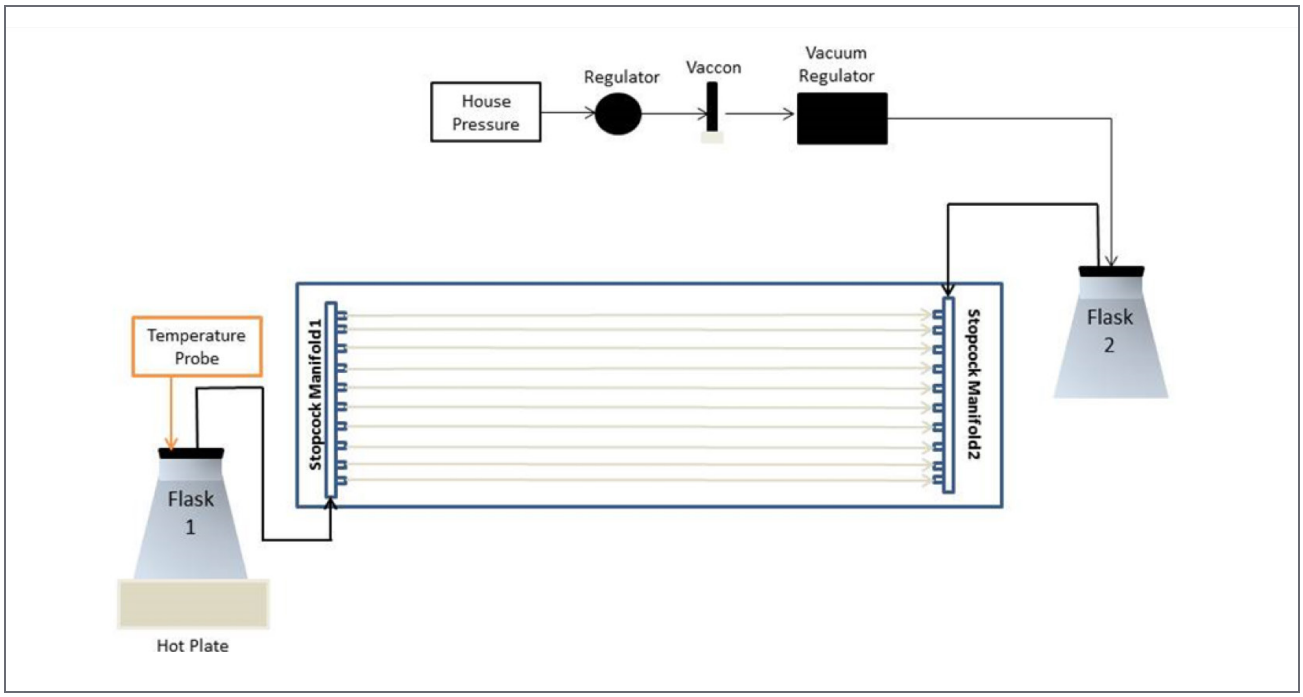

Figure 1: Vacuum Leak Test Method Setup

For this test, flask 1 was filled with 150 mL to 200 mL of 40°C degassed, distilled water. House pressure and the Vaccon vacuum generator were used to achieve a vacuum pressure of -20 kPa. Then, the stopcock in stopcock manifold assembly 2 was opened to draw water from flask 1 through the samples. After samples were primed with water, the stopcock in the stopcock manifold assembly 1 was closed. The samples were observed for leaks (i.e., air ingress) for 15 seconds.

The acceptance criteria for the vacuum leak test were for no ingress of air, as evident by the formation of bubbles within the sample, when filled with degassed, distilled water under a negative pressure of -20 kPa at 15 seconds at 40°C per ISO 8536-4:2010 A.2.3.

Pressure Leak at 20 PSI Test Method

For this test, the distal end of the sample was removed by cutting the line an inch above the cassette. The open end was then connected to a Nuitiv Clear connector. The sample was then primed with distilled water using a pressure regulator. Afterward, the sample was connected to a stopcock manifold, and the diaphragm of the cassette was also occluded. The pressure in the sample was raised to 20 psi and held for 15 minutes for observations.

The acceptance criteria of the pressure leak test was for no evidence of leakage in the form of liquid leaving the surface at 1 drop per second while under 20 psig for 15 minutes as per ISO 8536-8: 2004 A.3.4.

Results

Pressure Leak Test

All 45 samples met the acceptance criteria of no leakage after the sets were pressurized at 7.25 psi for 15 seconds at 40 +/- 1°C, providing a confidence of 90% with a reliability of 95%.

Vacuum Leak Test

All 45 samples met the acceptance criteria of no ingress of air during vacuum testing, as evident by the formation of bubbles within the set, when filled with degassed, distilled water subjected to a negative pressure of -20 kPa for 15 seconds at 40 +/- 1°C, thus providing a confidence of 90% with a reliability of 95%.

Pressure Leak at 20 PSI Test

All 45 samples met the acceptance criteria of no leakage after the sets were subjected to 20 psig for 15 minutes, thus providing a confidence of 90% with a reliability of 95%.

Conclusion

Based on the data above, the Nuitiv Clear needlefree connector may be compatible with commonly used chemicals in IV infusion.

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