ChemoClave® Chemical Compatibility

Thank you for your interest in the ICU Medical ChemoClave system. ICU Medical has tested its ChemoClave products extensively for compatibility with various chemicals which represent various therapeutic classes. The selection criteria for each of the drugs was based on a number of considerations including their widespread use, chemical composition and their known ability to interact with, or damage plastics. Results from this testing is applicable to all the ChemoClave product line for products which have the identical material formulations in their componentry. Results from the testing are applicable to the products listed below.

- Spiros® Closed Male Luer
- Clave® and MicroClave® and Neutron® Needlefree Connectors
- ChemoClave Bag Spikes
- ChemoClave Vial Spikes
- ChemoClave Administration Sets
- Diana Cassettes and Diluent Sets

ICU Medical manufactures all of its ChemoClave products, including Spiros®, Clave®, Tubing Sets, Bag Spikes and Vial Spikes exclusively without the use of Di(2-ethylhexyl) phthalate (DEHP), which is a commonly used chemical in medical plastics. DEHP is a known carcinogen which will leach, or release from the plastics when in contact with certain drugs or environmental conditions and travel down into the patient’s bloodstream. The absence of DEHP in all products protects patients from potential exposure to this chemical plasticizer. Microbial Ingress and sterility integrity has been verified independently for a 7-day period, where under a simulated use protocol The ChemoClave System was able to maintain complete sterility of the drug.

Specific drugs were selected to represent various therapeutic classes and chemical compositions. The ChemoClave system was exposed to the twelve selected antineoplastic drugs in their undiluted form. Drugs were diluted to three times their therapeutic value for testing with IV sets to represent the worst case exposure for administration equipment. Three separate tests were completed, including a functional integrity test, a drug stability test, and plastic migration test, to verify drug compatibility with the chemotherapy devices. To prepare test samples, each drug was infused through independent test samples, agitated, and then subjected to a storage protocol as noted in the table. Samples were place in refrigeration for a specified time period and then stored at room temperature for a specific time period. Devices were visually inspected during the storage period at various times and then leak tested to verify functional integrity.

All test results demonstrate that the ChemoClave products were compatible with these common therapeutic classes for a minimum of 24-hours and a maximum of 28-days for multi-use drugs. In the study results, drugs that were listed as ‘not tested’ for drug stability or plastic migration are provided in a single dose vials, and therefore per the drug manufacturer’s requirements, the drug must be discarded in less than 24-hours from its first access. This testing was limited to multi-dose drugs that allow for extended storage periods such as Cisplatin (up to 28 days), thus offering the longest potential opportunity for plastic migration or loss of drug stability. The following table includes a list of drugs which are known to fall into these common therapeutic classes and may therefore be considered compatible with the ChemoClave system.
Busulfan (Busulfex®) and Treanda® Liquid Formulation (bendamustine HCl) Specifics: All ChemoClave Administration Sets including the Clave and the Spiros are compatible with the diluted, solution forms of Busulfan at a 0.536mg/mL concentration, and Treanda (Liquid Formulation) at 350mg which reflects a 0.7mg/ml concentration in 500mL of 0.9% Sodium Chloride as the MSDS instruct. These concentrations represent the typical administration solution used for the delivery of these drugs to the patient. Test results show that the ChemoClave System met the functional requirements following exposure to 0.536mg/mL Busulfan over a four-hour period and 350mg Treanda over 2 hour and 45 minute period. The ChemoClave products are therefore deemed compatible with Busulfan and Treanda deliveries to the patient when in the diluted form. For compounding and preparation, the only device compatible with the undiluted, solution forms of Busulfan and Treanda, is the 13mm vented vial spike CH-72; no other ChemoClave products are compatible with undiluted Busulfan and Treanda.

Note: Treanda Lyophilized Powder formulation is compatible in the undiluted form with all ChemoClave components.

Abatecept injection (Orencia®) is not compatible with silicone according to the MSDS. All ChemoClave products use silicone components including silicone lubrications oils, and are therefore not compatible with Abatecept.

Sincerely,

Alison Burcar
Vice President, General Manager Infusion Systems

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