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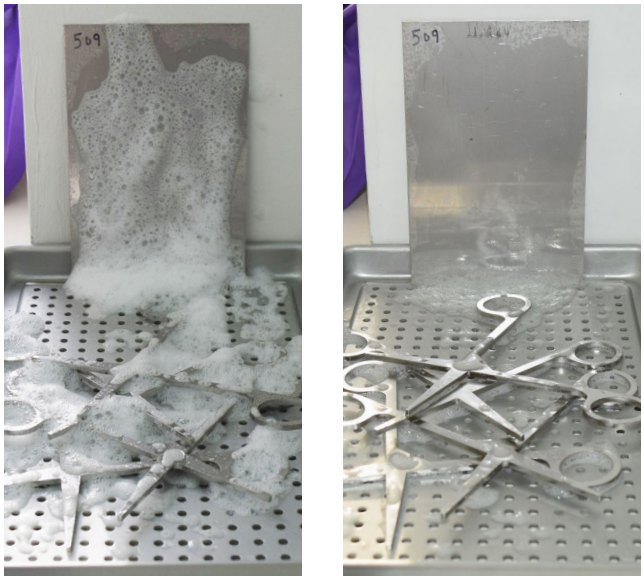
Characteristics of XEN Pretreatment Foams

Protein Removal

All XEN pretreatment foams are non-enzymatic. An internal study was performed on the base formulation of XEN pretreatment foams, comparing it to five market-leading commercially available enzyme-containing pretreatment products. Protein soil containing bovine serum albumen (BSA) and fibrinogen were applied to stainless-steel plates or surgical instruments. Various drying procedures and cleaning processes were used to simulate instrument use and reprocessing. The residual protein levels (that remained upon surfaces after cleaning) were measured using fluorescent protein detection, which uses an OPA based reagent that causes a fluorescence reaction.

The study demonstrated that all pretreatment products improved the protein removal during reprocessing. However, the non-enzymatic (XEN) base formulation was the most effective across the board, independent of protein drying time. Despite being enzyme-free these products showcase excellent performance demonstrating that enzymes are not essential for the effectiveness of this advanced formulation base.

Figure 1



Foam immediately after application

Foam after 10 minutes

Foaming Characteristics

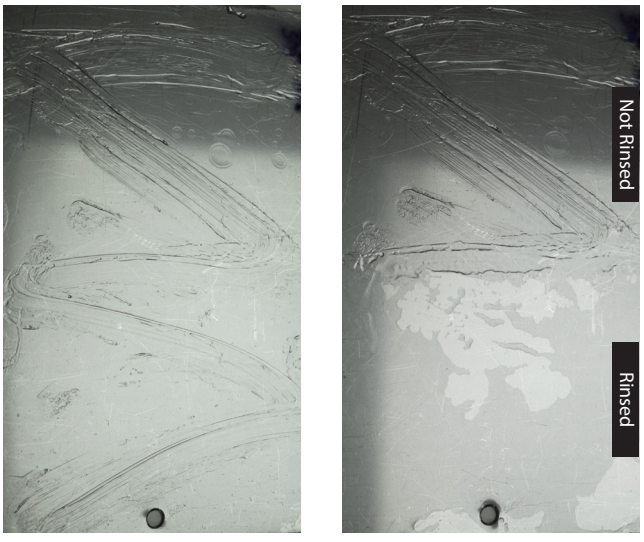
XEN pretreatment products are delivered by foam to the surface via foaming spray heads in either a manual trigger spray or an automatic spray. Because of the foaming characteristic of the products, the operator can easily identify where they have sprayed and ensure good coverage of all instruments being treated. The foam breaks down quickly so that sharps are visible helping to avoid the risk of sharps injury due to poor visibility of instruments. (Fig. 1).

Moisture Retention & Rinsability

The purpose of XEN pretreatment products is to keep soils moist during transport from point-of-use to the processing area. XEN pretreatment foams have been tested and demonstrated to remain moist for up to 100 hours in open air conditions*. Pretreatment products reduce the adverse effects of soils drying on the subsequent decontamination steps but are not intended to be used as a tool for leaving soiled instruments unprocessed for prolonged periods of time.

Testing to confirm the moisture retention characteristics of XEN formulations was performed over 100-hours using stainless-steel panels sprayed with pretreatment products. After 100 hours in open-air conditions (at ambient temperature), the coating of product remaining on the surfaces was still wet and able to be moved around when touched. The image below shows the pretreatment in a zigzag pattern after 100 hours. The remaining pretreatment product was then tested for ease of rinsing by rinsing off half of the test panel under running water for 5 seconds at 20°C (68°F). The product was readily rinsed away. (Fig. 2).

Figure 2



Foam is still wet after 100 hours

Foam rinses easily after 100 hours

Xcelerate+ & Xcelerate+ Lumen Propellant

XEN Xcelerate+ and Xcelerate+ Lumen are automated spray containers designed to deliver foam pretreatment spray to soiled medical devices prior to reprocessing. This automated delivery format is advantageous for rapid wide spray coverage of instruments in trays or baskets and precision application for lumens without the operator fatigue and variable pressure of manual trigger spray units. Delivery of the liquid in foam form limits the potential for aerosolization.

The propellant used in the containers is known as 1234ze. It is a new generation HFO with no flammability classification, very low human toxicity, and minimal environmental impact (ozone depletion/greenhouse gas effect).

This new propellant is widely selected for use in personal care and is FDA approved for medicinal products such as metered dose inhalers (MDI). A group toxicology study on MDI usage[1] determined a person with an MDI exposure of HFO-1234ze at about 500 mg/60 kg would have "...very large margins of safety". Therefore, it is considered sufficiently safe for use in the OR/ED.

This propellant is classified as a low physical and environmental hazard. It has a low global warming potential (GWP) and is not classified as flammable. Therefore, it does not require any additional labeling or warnings beyond those required due to the container being pressurized.

*It is not recommended per AAMI standard or professional society guidelines to leave soiled instruments sit without reprocessing for extended periods of time. Best practice is to reprocess soiled instruments as soon as possible after use. Local and national standards and guidelines should always be followed.

[1] Giffen, P. S., Kilgour, J. D., Jacobsen, M., Thacker, K., & Holmberg, A. A. (2024). The Nonclinical Assessment of Trans-1,3,3,3-tetrafluoropropene (HFO-1234ze (E)), a Near Zero Global Warming Potential Propellant for Use in Metered Dose Inhalation Products. International journal of toxicology, 43(1), 4–18. https://doi.org/10.1177/10915818231206025