Clinical Questions (FAQs): XEN Cleaning Chemistries

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What is the shelf life for XEN Detergents?

The shelf life provides a time frame in which products are known to deliver performance to specification. Customers should not rely on products to deliver optimal performance beyond the validated shelf-life period or expiry date.

The shelf life is established by conducting studies on products to test against their quality control specification(s) before and after storage. Where time is limited for new formulations, accelerated storage is carried out by storing samples at elevated temperatures to simulate an accelerated passage of time. Where products are released with accelerated shelf-life studies, these are always followed up with real-time studies.

Additionally, depending on the product type, further relevant physical or chemical tests are carried out on samples before and after storage. These may include pH, foaming properties, and quantification of activity (e.g., acidity, alkalinity, or chelating agents).

Enzyme stability is one area specifically focused on in shelf-life testing. While enzymes enhance cleaning processes significantly, at the end of the product's shelf life, it is imperative that their stability in formulation perform as though it were a freshly made product.

XEN Product	Shelf Life* (months)
Xcelerate	18
Xcelerate+	24
Xcelerate+ Lumen	24
Enzymatic	24
Enzymatic+	24
QuadX	24
Neutral	24
Neutral+	24
Universal	24
Universal+	24
Rinse	36
Instrument Lubricant+	36
Instrument Shine	36
Chamber Shine	24
Chamber Shine+	36

*From date of manufacture

As XEN Pretreatment Products (Xcelerate, Xcelerate+, and Xcelerate+ Lumen) are non-enzymatic, how is protein removal performance?

All XEN pretreatment products 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 or fibrinogen) was applied to stainless-steel plates and surgical instruments. Various drying procedures and cleaning processes were used to simulate instrument use and reprocessing. The residual protein levels remaining after cleaning were measured using fluorescent protein detection.

The study demonstrated that all pretreatment products improved protein removal during reprocessing. However, the non-enzymatic (XEN) base formulation was the most effective across the board, independent of protein drying time.

How do the XEN Pretreatment products perform for moisture retention and rinsibility?

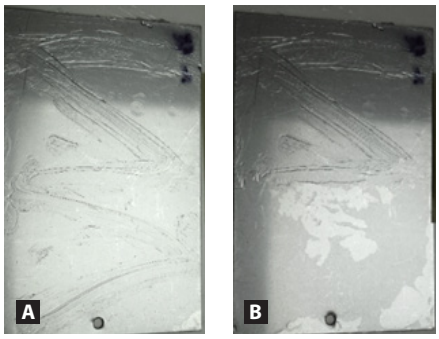


Figure 3: Film is still wet after 100 hours (**A**). Bottom half rinses easily after 100 hours (**B**).

The purpose of XEN pretreatment products is to keep soils moist during transport from point-of-use and 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 may reduce the adverse effects of soil drying on instruments during subsequent decontamination steps but are not intended to be used as a tool for leaving soiled goods unprocessed for prolonged periods of time intentionally.

Testing to confirm the moisture retention characteristics of XEN formulations was performed over a period of 100 hours. Stainless-steel panels were sprayed with pretreatment products and left out in open-air conditions at ambient temperature. After 100 hours, the film of product remaining on the surfaces was still wet and able to be moved around when touched. The images to the left show where the film has been spread in a zigzag pattern after 100 hours. The remaining wet film was then gauged for ease of rinsing by rinsing off half of the test panel under running water for 5 seconds at 20°C (68°F). The film was readily rinsed away. (Fig. 3).

**It is not recommended, per AAMI standard or professional society guidelines, to let 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.*

What are the foaming characteristics of XEN Pretreatment Products?

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 the instruments being treated. (Fig. 1).

The foam then breaks down quickly so that sharps are visible, helping to avoid the risk of sharps injury due to poor visibility of instruments. (Fig. 2).

Figure 1: Foam immediately on application

Figure 2: Foam after 10 minutes

What are the propellant characteristics for Xcelerate+ & Xcelerate+ Lumen?

XEN Xcelerate+ and Xcelerate+ Lumen are pressurized containers for delivery of foam pretreatment spray to soiled medical devices prior to reprocessing. The pressurized container 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 HFC hydro-fluoro-olefin (HFO) with no flammability classification, very low human toxicity, and minimal environmental impact (ozone depletion/greenhouse gas effect). The new propellant is widely selected for use in personal care and medicinal products such as metered-dose inhalers.

The propellant used in these automatic sprays was selected because it is classified as a low-risk 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.

Are XEN Neutral and XEN Neutral+ acceptable to use with ophthalmic instruments?

Yes, XEN Neutral and XEN Neutral+ are formulated specifically with ophthalmic instruments in mind. They do not contain enzymes, and with an efficient surfactant system, they give favorable cleaning performance without the risk of enzyme-related complications in eye surgery.

As with all other surgical instruments, ophthalmic instruments require reprocessing to ensure cleanliness before reuse. However, unlike general surgical instruments, the use of enzyme-based detergents on ophthalmic instrumentation is not recommended.

Improper cleaning and/or rinsing can pose a risk to patients to postoperative infectious endophthalmitis (PIE) and toxic anterior segment syndrome (TASS)[1] due to the small volume of the eye and its sensitivity to minute amounts of chemical or microbial contaminants.

Using enzymatic detergents for decontaminating intraocular surgical instruments is problematic.[2] Previous studies in both animals and humans have shown that enzymatic detergents are toxic to the corneal endothelium.[3-4] It is the position of the Ophthalmic Instrument Cleaning and Sterilization (OICS) Task Force that enzymatic detergents should not be routinely required for these instruments. Studies have shown that while following manufacturers IFU, even minute enzyme residue left on intraocular instruments can cause TASS.[2]

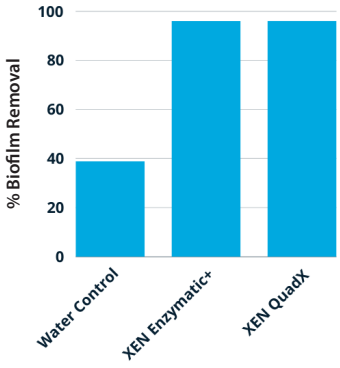
Do XEN Enzymatic+ and QuadX help with biofilm removal?

Yes, Laboratory testing was performed to provide evidence of biofilm removal. Small polyethylene terephthalate glycol (PETG) slides were placed in narrow bore tubing of about ≈3 mm inner diameter and water spiked with a culture of biofilm forming bacteria obtained from dental unit waterlines with added nutrients that were recirculated for 2 weeks to allow a biofilm to build up.

The developed biofilm plates were rinsed with clean water, then the tubes were filled with test product solution and stored at 40°C (104 °F) for 30 minutes without agitation. Each tube was then rinsed with water and the biofilm slide was removed, stained with crystal violet, and assessed microscopically for biofilm.

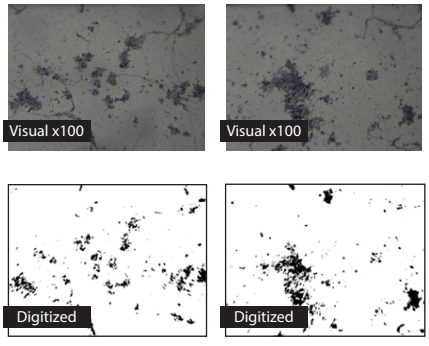
The resultant micrographs were digitized and analyzed via image analysis software to resolve the images into pure black and white to give a pixel count to measure the coverage percentage of the biofilm.

The ratio of biofilm to background (test slide) is then calculated to generate a % biofilm coverage. The % biofilm coverage is then used to calculate % biofilm removal. For each test, 4 images were resolved from each slide to gain an average.

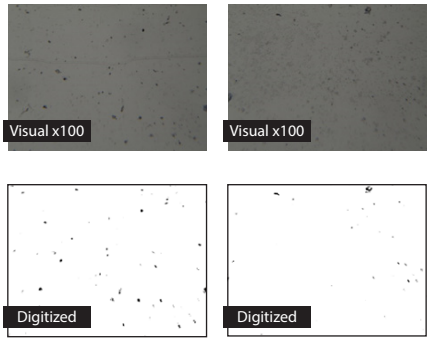


Biofilm removal testing with both XEN Enzymatic+ and QuadX demonstrated a >96% biofilm removal when compared with water, which showed only a 38.9% biofilm reduction.

Control Image Analysis



Test Product Image Analysis



Are XEN Rinse & XEN Instrument Lubricant+ Detergents permeable to steam and ethylene oxide?

XEN Rinse and XEN Instrument Lubricant+ are dosed into the final rinse water of the reprocessing cleaning cycle. Residues of these products remain on instrument surfaces during the subsequent sterilization process. Both products have been tested to demonstrate their presence on surfaces does not adversely affect sterilization by steam (autoclaving) or ethylene oxide (EO).[5]

To demonstrate this, the products were applied to sterile stainless-steel plates that were inoculated with spores and then exposed to a sterilization cycle. The plates were then analyzed to detect any surviving spores.

Test results demonstrate the products do not interfere with the sterilization of surgical instruments by steam sterilization or EO sterilization.

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