

Technical Data Monograph

**Cleaning Efficacy of Prolystica® Enzymatic Presoak and Cleaner
Comparison to other Enzymatic Products**



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Background

There are a multitude of soils that present difficulties in the cleaning of surgical instruments. The most common and some of the most difficult to clean of these soils are protein and fat. Real world conditions would dictate that these soils are present on instruments together. Therefore, the ability to clean all of these soils with one product is clearly an advantage in productivity, turn around time, and cost.

There are a variety of ways to clean surgical soils, one of these mechanisms of cleaning being the use of enzymes. At neutral pH, enzymes are very effective cleaners. Protease enzymes are effective against protein and lipase enzymes are used for fatty soils. However, enzymes are not the only component of a product that determines the ability to clean. Surfactants play a major role in cleaning soils from a surface, especially fats. An optimized surfactant system has the ability to clean fatty soils better than lipase enzymes, as will be demonstrated with the following testing.

Purpose

Prolystica® Enzymatic Presoak and Cleaner is a 2X concentrate, dual protease enzymatic detergent designed for use in manual cleaning and automatic washers/disinfectors for the processing of surgical instruments. The purpose of this study was to compare the cleaning efficacy of Prolystica Enzymatic Presoak and Cleaner and a number of additional enzymatic products including those containing lipase enzymes against a combination of surgical soils.

Methods

Method 1: Evaluation of Protein Cleaning Using a Protein Film Strip Test (Gelatin)

The protein film strip test uses exposed and developed black and white 35-mm photographic film. The photographic film is coated with an emulsion layer composed of gelatin, which is a protein. The film strip is initially black. As the enzymatic cleaner breaks down and removes the protein, the film becomes clear. Comparisons between enzymatic products were achieved by measuring the time required to breakdown and remove the protein from the test film and thus turn it from black to clear.

The enzymatic products were prepared at recommended use dilution [Table 1] in tap water at 50°C (122°F). The film strips were then suspended in the product dilutions with agitation. The time to completely clean was recorded. All samples were tested in triplicate.

Table 1 Enzymatic Products Tested

Supplier	Product	Test Use
STERIS Corporation	Prolystica® Enzymatic Presoak and Cleaner	½ ounce/gallon
Ecolab® Inc. Huntington® Brand	Asepti-zyme™ Instrument Presoak and Cleaner	1 ounce/gallon
Ecolab® Inc. Huntington® Brand	Rapid-zyme™ Instrument Presoak and Cleaner	1 ounce/gallon
The Ruhof Corporation	Endozime® AW Triple Plus with APA	½ ounce/gallon
Cardinal Health	V. Mueller® Dual Enzy-Clean® Low Suds Enzymatic Pre-Soak and Detergent	2 ounce/gallon
Medline Industries, Inc	Medline Enzymatic Detergent and Pre-Soak	2 ounce/gallon

Method 2: Evaluation of Fatty Soil Cleaning Using Crisco

Fatty soil (Crisco) was applied to stainless steel coupons and allowed to dry overnight. The coupons were weighed and then placed in an enzymatic product solution (Table 2) at their highest label use dilution in 50°C tap water. The solutions were agitated during cleaning using a stir bar. The study was conducted so that percent removal at two minutes 45 seconds and 30 minutes were both evaluated. After the allotted time of exposure, the coupons were then removed from the enzyme solution and rinsed with deionized water. They were allowed to dry, the percent removal was determined by weight, and photographs were taken. All samples were tested in triplicate.

Table 2 Enzymatic Products Tested

Supplier	Product	Test Use
STERIS Corporation	Prolystica® Enzymatic Presoak and Cleaner	½ ounce/gallon
The Ruhof Corporation	Endozime® AW Triple Plus with APA	½ ounce/gallon
The Ruhof Corporation	Orthozime®	1 ounce/gallon

Method 3: Evaluation of Synthetic Surgical Soil Cleaning Using: Blood/Bone/Fat/Tissue

Simulated surgical soil consisting of blood, bone, fat and tissue was applied to hemostats and dried in a 50°C oven for one hour. The hemostats were weighed and then placed in a solution of the enzymatic products (Table 3) at their highest label use dilution in 50°C tap water with agitation for 10 minutes. At 10 minutes, the hemostats were removed from the enzyme solution and rinsed with deionized water. They were allowed to dry, the percent removal was determined by weight, and photographs were taken.

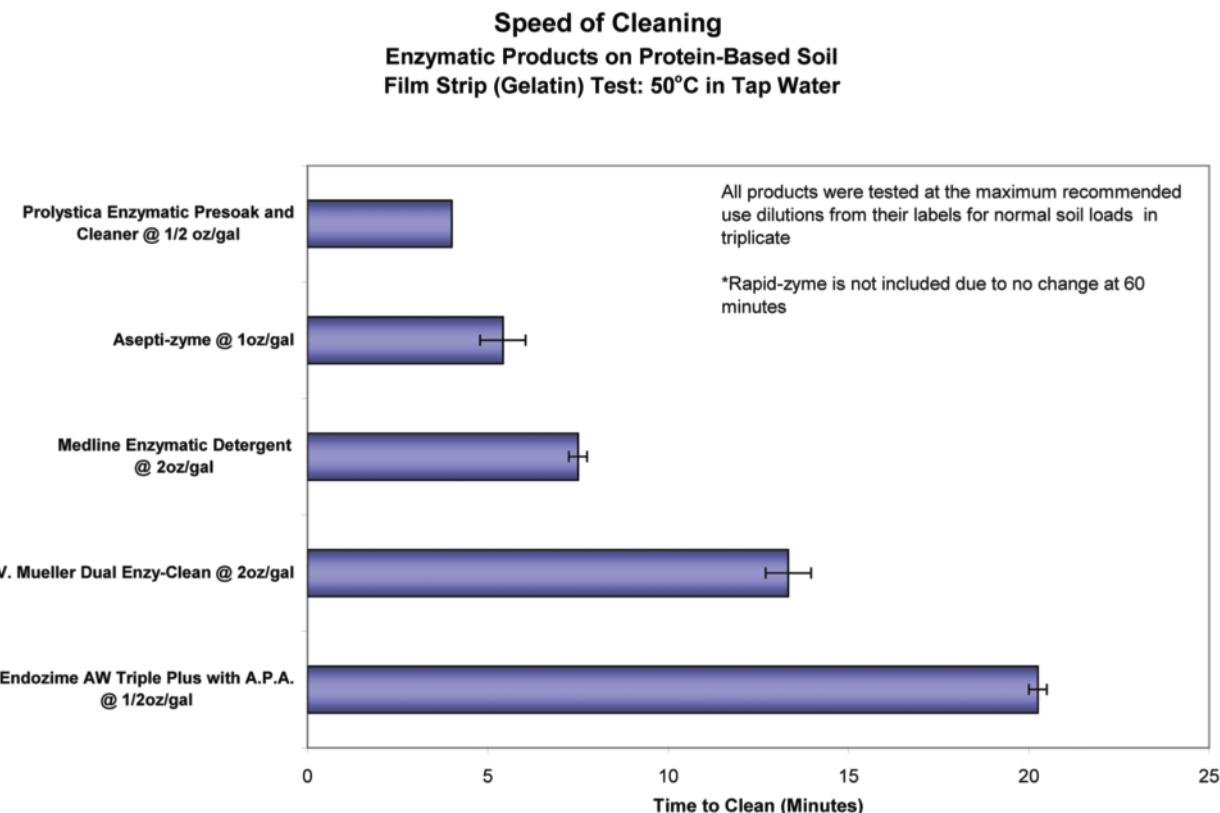
Table 3 Enzymatic Products Tested

Supplier	Product	Test Use
STERIS Corporation	Prolystica® Enzymatic Presoak and Cleaner	½ ounce/gallon
Ecolab® Inc. Huntington® Brand	Asepti-zyme™ Instrument Presoak and Cleaner	1 ounce/gallon
Ecolab® Inc. Huntington® Brand	Rapid-zyme™ Instrument Presoak and Cleaner	1 ounce/gallon
The Ruhof Corporation	Endozime® AW Triple Plus with APA	½ ounce/gallon
The Ruhof Corporation	Orthozime®	1 ounce/gallon
Cardinal Health	V. Mueller® Dual Enzy-Clean® Low Suds Enzymatic Pre-Soak and Detergent	2 ounce/gallon
Medline Industries, Inc	Medline Enzymatic Detergent and Pre-Soak	2 ounce/gallon

Results

Method 1: Evaluation of Protein Cleaning Using a Protein Film Strip Test (Gelatin)

Prolystica® Enzymatic Presoak and Cleaner at 1/2 oz/gal completely removed the protein from the film strip by four minutes. Asepti-zyme™ at 1 oz/gal and Medline Enzymatic Detergent at 2 oz/gal were able to remove the protein soil between five and 10 minutes. V. Mueller® Dual Enzy-Clean® at 2 oz/gal removed the soil within 15 minutes and Endozime® AW Triple Plus at 1/2 oz/gal was able to achieve cleaning at 20 minutes. However, Rapid-zyme™ at 1 oz/gal caused no change to the film strip even after 60 minutes.

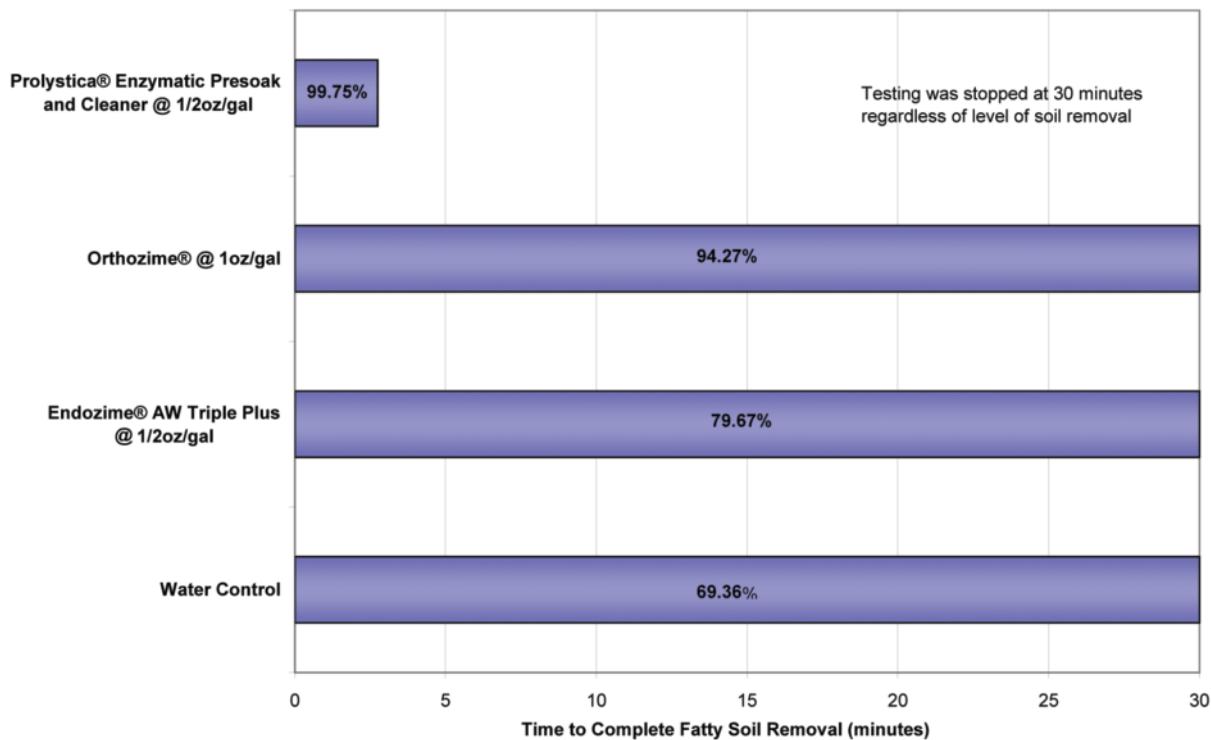


Method 2: Evaluation of Fatty Soil Cleaning Using Crisco

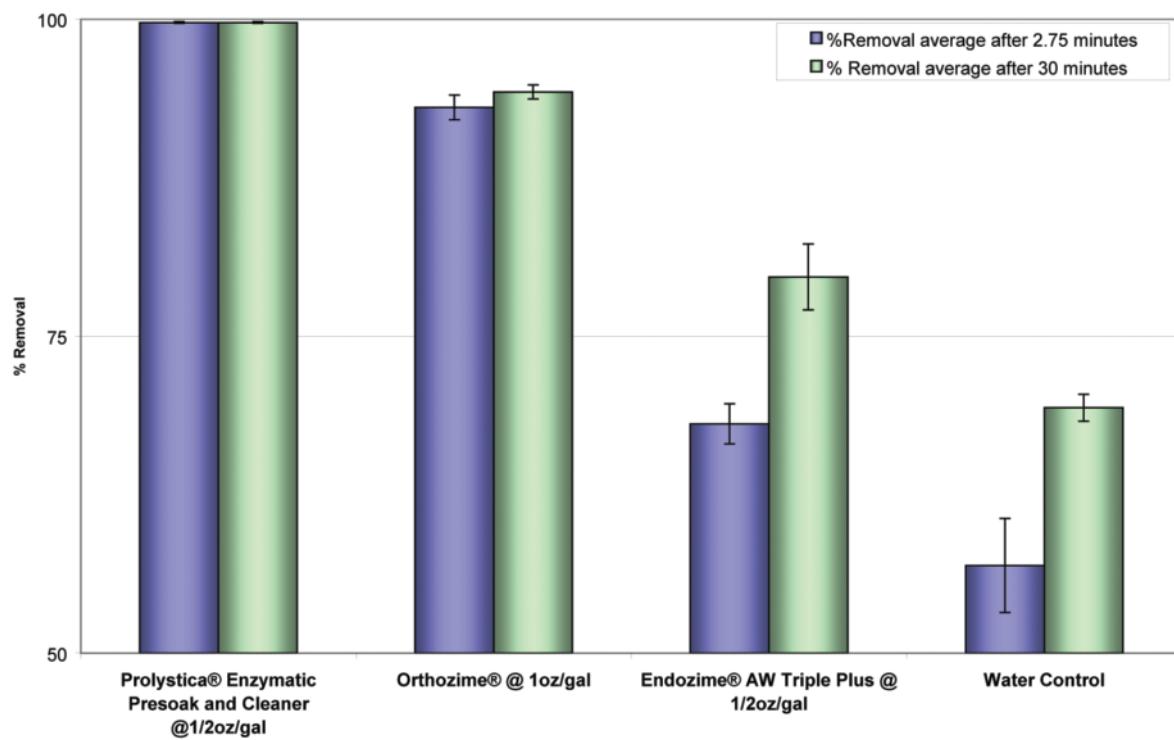
Prolystica® Enzymatic Presoak and Cleaner at 1/2 oz/gal achieved 99.8% removal of the Crisco at 2 minutes 45 seconds. Orthozime® at 1 oz/gal had 90% removal at 2 minutes 45 seconds and 94% removal at 30 minutes, but there was substantial residue remaining at both time points. Endozime® AW Triple Plus with APA at 1/2 oz/gal removed 68% of the fatty soil within the 2 minutes 45 seconds; however there was not much improvement at 30 minutes with only 80% removal. The water control had a baseline of 57% removal at 2 minutes 45 seconds and 69% removal at the 30 minute time point.

Cleaning Efficacy (Speed and Performance)

**Time to Clean Fatty Soil (Crisco)
Agitated Immersion @50°C (122°F)**



**% Removal of Fatty Soil (Crisco) from a Stainless Steel Surface
Agitated Immersion @ 50°C (122°F)**



**Prolystica® Enzymatic Presoak
and Cleaner @ ½ oz/gal**



**Fatty Soil Removal
@ 2 Minutes 45 Seconds**

Orthozime® @ 1 oz/gal



**Fatty Soil Removal
@ 30 Minutes**

**Endozime® AW Triple Plus with APA
@ ½ oz/gal**



**Fatty Soil Removal
@ 30 Minutes**

Water Control



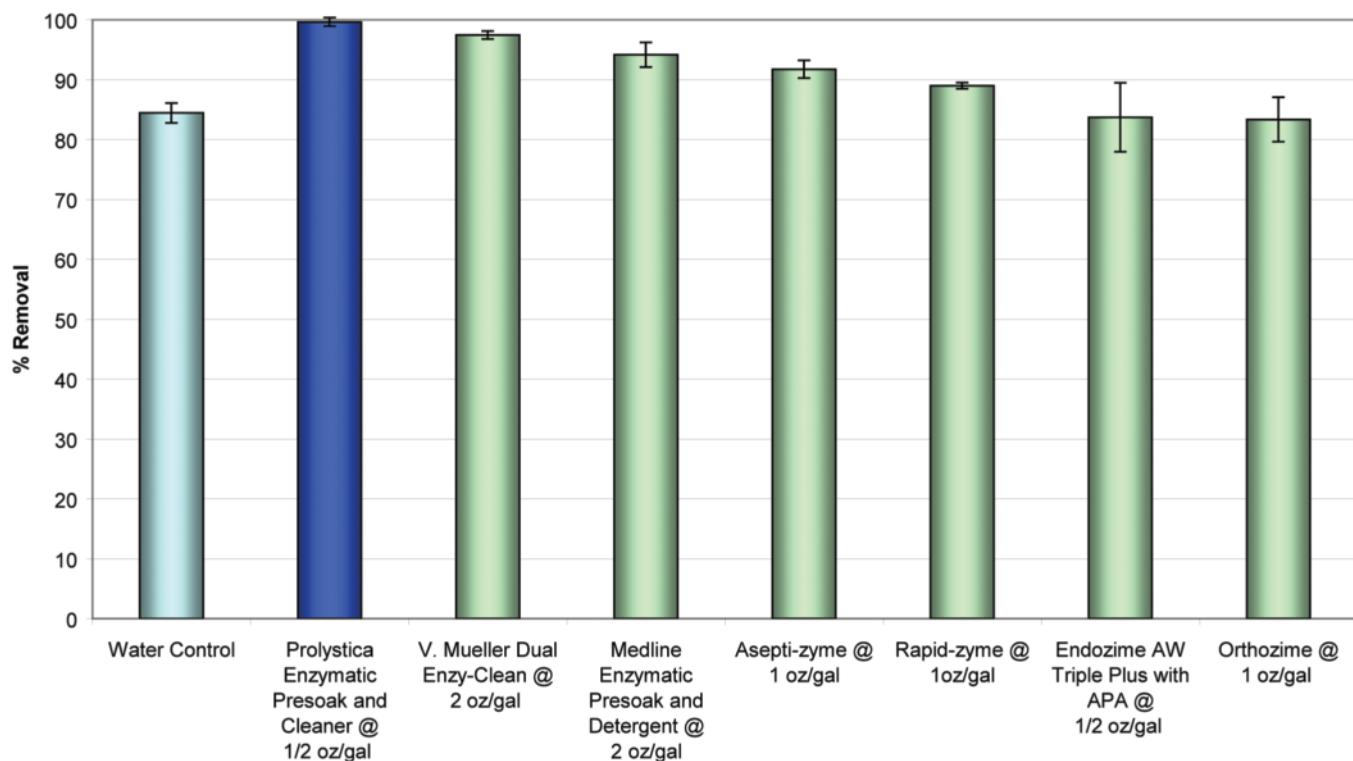
**Fatty Soil Removal
@ 30 Minutes**

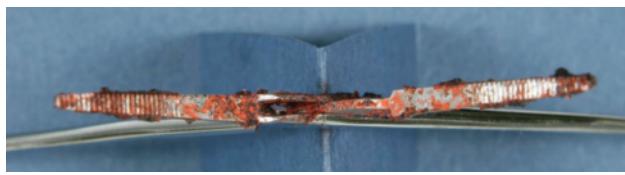
Method 3: Evaluation of Synthetic Surgical Soil Cleaning Using: Blood/Bone/Fat/Tissue

Prolystica® Enzymatic Presoak and Cleaner at $\frac{1}{2}$ oz/gallon cleaned the hemostats at 10 minutes with 99.6% removal. V. Mueller® Dual Enzy-Clean® and Medline Enzymatic both used at 2 oz/gal (4X the amount of Prolystica Enzymatic Presoak and Cleaner) had 97% and 94% removal by weight. However, there was noticeable soil residue on the instruments for both products, especially in the box locks area of the hemostats. Asepti-zyme™ and Rapid-zyme™ at 1 oz/gal had percent removals of approximately 90%. Endozime® AW Triple Plus $\frac{1}{2}$ oz/gal and Orthozime® at 1 oz/gal offered no cleaning efficacy with percent removal being equal to that of water alone.

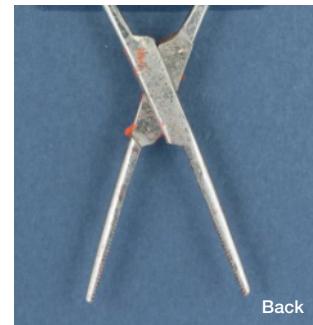
Cleaning Efficacy

Immersion Test: % Removal of Blood/Bone/Tissue/Fat Soil at 10 minutes at 50°C

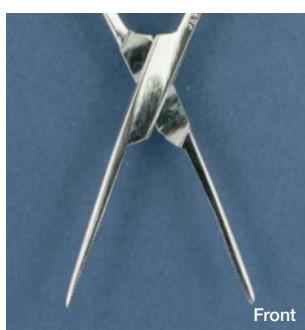




Untreated



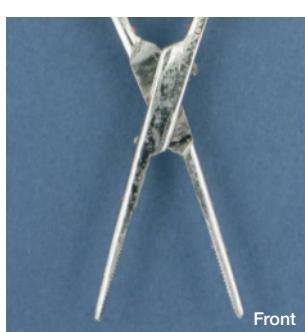
Water Control



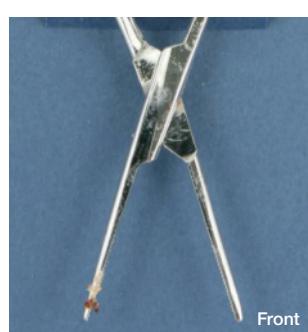
Prolystica® Enzymatic Presoak and Cleaner
(1/2 oz/gal)



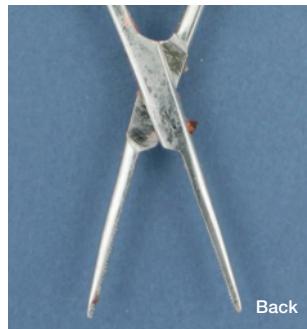
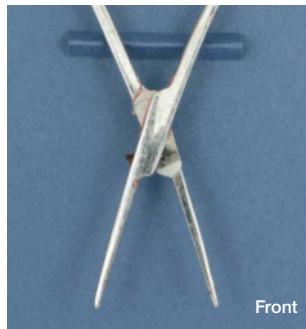
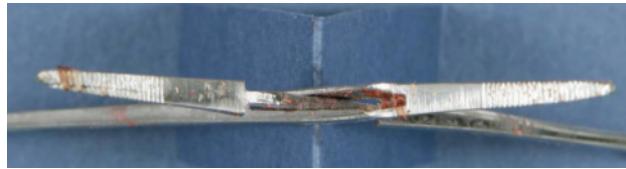
V. Mueller® Dual Enzy-Clean® (2 oz/gal)



Medline Enzymatic Detergent and Pre-Soak
(2 oz/gal)

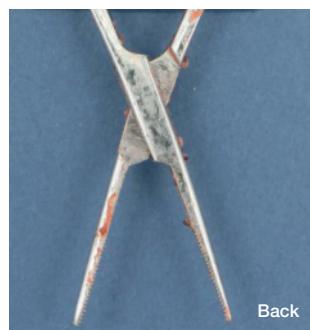


Asepti-zyme™ Instrument Pre-Soak and Cleaner
(1 oz/gal)



**Rapid-zyme™ Instrument Pre-Soak and Cleaner
(1 oz/gal)**

Orthozime® (1 oz/gal)



**Endozime® AW Triple Plus with APA
(1/2 oz/gal)**

Conclusion

Prolystica® Enzymatic Presoak and Cleaner is effective against a variety of soils, including protein fat, bone chip, and tissue soils. This neutral pH enzymatic cleaner removes all soils quickly and completely. No competitor was able to attain either the effectiveness of cleaning or the speed of cleaning demonstrated by Prolystica® Enzymatic Presoak and Cleaner even when used at up to 4X the concentration.

References: Research and Development Notebook numbers:
6470: 18-19; 6470: 40-47; 6518: 31, 50-60

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