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Learning Objectives

1. Discuss the true benefits of enzymatic cleaners and their purpose and position in the decontamination process.

2. Explain the advantages of using dual-enzyme chemistry rather than multi-enzyme chemistry.

3. Describe the parameters necessary in sterile processing departments and GI Labs for effective performance and cleaning when using an enzymatic cleaner.

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What, how and why:

Enzymatic instrument cleaning products in healthcare environments

by C. Wayne Root, RN, Nancy Kaiser and Christopher Antonucci

Enzymatic cleaning chemistries are used throughout healthcare facilities to aid in the cleaning of medical instrumentation and devices. They are the workhorse products in both endoscopy and sterile processing/central services areas.

Enzymatic cleaning products are used as a precursor, to help other detergents work properly. They are used as presoaks, during manual cleaning of delicate items and endoscopes, and as the first stage of most automated washer processing cycles. Because they are an important part of most cleaning processes in healthcare facilities, it is important to have a thorough understanding of enzymatic cleaner capabilities and limitations in order to use them effectively and assure productivity and safety in your department.

What *is* an enzyme? How does it work?

Enzyme cleaning products are made up of a variety of components, the most critical of which are the enzymes themselves. Enzymes are part of the class of compounds known as *proteins*. Proteins are large, naturally occurring molecules made up of amino acids with a very complex structure that drives their functionality. The structure allows the reactants (in this case soil and water) to be held in conformation close enough to each other to give the reaction a "push" on the molecular level. The enzymes are effective at very low concentrations and are not consumed during the process. Through the use of enzymes, reactions that would normally require an alkaline pH (hydrolysis, for instance) can take place rapidly at a neutral pH. This results in better compatibility with instrument component materials and thorough cleaning with minimal mechanical action (brushing, spraying or agitation, for example).

There are several types of enzymes in enzymatic cleaning products. These include **proteases**, **lipases**, **amylases** and **cellulases**.

Proteases break down proteins by hydrolysis of the peptide bonds between amino acids. Proteins tend to be very large and water insoluble molecules. Proteases take the large insoluble molecules and break them down into smaller more water soluble ones. Although proteases are specific to breaking bonds in proteins, the proteases used in enzymatic cleaners for the healthcare environment are non-specific they cleave peptide bonds in a wide variety of protein soils such as blood, mucous, tissue and serum. Different types of proteases with complementary pH and temperature profiles can be combined to enhance their effectiveness over broader pH and temperature ranges.

Lipases are the other enzymes that have a practical application in the healthcare environment. Lipases work by hydrolyzing ester bonds in fats and oils such as adipose tissue and triglycerides. These fat and oil molecules are, in contrast to proteins, not very large but also tend to be insoluble in water.

Amylases break down starch or carbohydrates, and cellulases, as their name implies, break down cellulose. Amylases and cellulases are typically included in household products such as powdered laundry detergents to break down gravy and grass stains on cloth, but are not typically needed in cleaning formulations for surgical instrumentation.

Multi-enzymatic cleaners: The facts, not fiction

Cleaning chemistries are formulations that combine inert and active ingredients. The ingredients work together to remove soil from a surface. These formulations can include surfactants (Surface Active Agents), solvents, and enzymes. Inclusion of a variety of ingredients helps to ensure that the chemistry can clean a broad spectrum of soils. This is important because surgical soils can include a variety of different substances, including proteins and lipids.

Water is the most widely used ingredient in the cleaning process. It is used as the See **SELF-STUDY** on page 53

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source of impingement (spray force) in automated washers as well as the main diluent of cleaning chemistries. Typically greater than 98% of what is used in any cleaning process is water. Water is readily available and inexpensive, but has some limitations. Water tends to bead up on surfaces as a result of its relatively high surface tension; so ironically, water does not wet surfaces well.

Surfactants act at surface interfaces (in this case between water and soil) to help lower the surface tension of water and to help wet and penetrate soil on medical instruments. Surfactants can also emulsify and solubilize water-insoluble ingredients such as lipids (both biological and synthetic). A good enzymatic detergent will use a well-designed surfactant system to enhance penetration of protein-based soil. This penetration improves access to the peptide bonds and dissolves the proteins into solution as the enzymes break them down, all of which speeds the cleaning process. The right surfactant system can also prevent soils from re-depositing on instrument surfaces once they have been removed, by keeping the soil suspended in the water.

Because proteases break down proteins, and enzymes are proteins, it is important to evaluate the stability of each enzyme included in an enzymatic formulation, especially any products containing different types of enzymes, because some enzymes may not be stable in the presence of proteases. Because of this tendency to be unstable in combination, it is not recommended that non-specific proteases be mixed with other types of enzymes.

It is not the presence of individual ingredients that provides optimal cleaning outcomes, but how those ingredients work



Figure 1. Impact of the proper surfactant system on the effectiveness of different enzymatic cleaners at removal of blood, fat, tissue and bone chips from hemostats. These hemostats were cleaned using agitated immersion for 10 minutes at 50°C using cleaners at 1/2 oz per gallon.

together towards the performance of the product as a whole. It's the combination of proteases with the proper surfactants, for example, that ensures superior cleaning efficacy for all common surgical soils.

A properly formulated enzymatic cleaner with the right surfactant choices will result in optimal lipid removal without the use of lipase enzymes. Although multienzymatic products have been positioned in the healthcare market as being superior based on a "cocktail" of enzymatic ingredients, the truth is that enzymes other than proteases are not required for effective cleaning. In other words, variety is not necessarily quality.

Other factors: Soils, pH and temperature

How rapidly and thoroughly an enzymatic product works on a soil is dependent on a number of factors. These include the amount and type of soil, the concentration of enzymatic product used, pH and temperature.

Surgical instrumentation will present a mix of different types of soils, based on the procedure being performed. Protein-based soils such as blood and serum are the most common in general surgery, but with the increase in orthopedic surgeries, the amount of lipid based soils is increasing. Some of the most difficult soils to clean are the substances found within the joints, such as synovial fluid. This fluid is made up of a complex mixture of compounds, including proteins, glycoproteins, disaccharides and phospholipids. In addition, synthetic lipids that accumulate in patients who have incorporated "light" products into their diets are very difficult to clean from

endoscopes and instruments. Also, the ability to clean any soil is made more difficult when it has been allowed to dry. It's important to keep the soil moist, or use a product with an adequate amount of surfactant to "wet" the soil and emulsify and solubilize across a wide spectrum of soils, to avoid dried-on matter.

The pH of a cleaning environment is largely driven by the type of water used (hard, soft or purified), the product pH, and by the soil itself. Most bodily fluids are pH neutral, but not always. The ideal enzymatic product should contain dual pro-



Figure 2. Temperature dependence of cleaning time using enzymatic cleaners against a protein-based soil (gelatin film strip). All cleaners were used at the highest label-recommended concentration.

teases to cover a wider range of potential pH levels, and some buffering capacity to maintain the pH at a level that allows the product to be most effective.

Enzymatic products can be effective over a wide range of temperatures. However, since enzymes are proteins and their protein structure drives their functionality, there are some temperature factors to be aware of when using enzymes. The optimal range for use of protease enzymes is between 38°C/100°F and 60°C/140°F. Protease enzymes are more effective on protein soils as temperatures are increased from room temperature to 60°C/140°F. However, after temperatures reach 65°C/ 149°F, the enzyme's structure begins to unravel and its functionality is irretrievably lost.

Enzymatic cleaners are a great beginning....but not all you need

Enzymatic cleaners help to set the stage for the next step in the process. By removing the first layer of soil from medical instruments, they reduce bioburden and help break down the proteins that adhere to surfaces. The right enzymes in the right formulation with the proper surfactant system will result in a fast-acting product that literally lifts soil off instruments into the cleaning solution.

The use of enzymatic cleaners helps make the next step in the cleaning process more effective, and allows for the use of neutral pH cleaners, which are much more compatible than alkaline chemistries for delicate instruments made with soft metals, but See SELF-STUDY on page 54

SELF-TEST ANSWERS: 1. A, 2.C, 3. D, 4.A, 5. A, 6.C, 7.D, 8. D, 9. C, 10.D

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may not break down proteins as well as enzymatic or alkaline cleaners.

When used before alkaline chemistries, enzymatic cleaners can enhance the effectiveness of the alkaline chemistry used in the next step. Alkalinity is non-specific in its reactivity so it can be used up when there's a high organic load and therefore not be available to break down other soils. The use of an enzymatic cleaner as a first step not only enhances efficacy of the alkaline cleaner, but it also allows a lower level of alkalinity to be used for washing. Lower alkalinity means higher compatibility with a larger number of delicate medical instruments. Also, following the enzymatic cleaner with another cleaning chemistry helps to rinse the enzyme proteins off instrument surfaces better.

Enzymatic cleaners in your healthcare facility: What you should know

- Formulation quality: If an enzymatic product is doing its job, one sniff will tell you. Instruments that are clean smell clean; instruments that come out of automated washing systems smelling of blood have not been thoroughly cleaned. Not all enzymatic cleaners exhibit the same performance characteristics. The mere presence of an ingredient on the label does not make the formulation effective. If you want assurance that an enzymatic product really works as the manufacturer claims, it's important that documentation or other proof exists to support those claims.
- Compatibility: Since one of the benefits of enzymatic cleaners is their ability to provide cleaning performance at neutral pH, the enzymatic product you choose should document broad spectrum compatibility with the component materials used in medical instruments and automated washing systems. This should include stainless steel, soft metals such as aluminum, copper and brass, and a wide variety of plastics. Adequate testing should have been conducted and documented for any enzymatic cleaner to illustrate any/all potential for degradation of scope materials. This testing includes the monitoring of visual, tactile and weight changes of any metal or plastic material used as part of an endoscope.

Enzymatic formulations should not only protect against instrument degradation, but they should go one step further and provide evidence of protection from the

damaging effects of water, since water itself is corrosive. Furthermore, surgical and procedural instruments and equipment are expensive to replace, so any cleaning product cost assessment should include the potential impact of that product on replacement and refurbishment budgets.

 Concentrated chemistry benefits: Enzymatic formulations can be effective at low concentrations. The amount of product needed depends on the soil load, so the range of recommended

concentrations on the product label should allow for a range of soil loads. It is also helpful to the facility if the product is concentrated; this can lower the required room for inventory of product and make the containers easier to handle.

- The GREEN factor: Concern for our global environment is reflected in an increased emphasis on "green" products. Enzymes themselves are organic in nature, but enzymatic cleaners are formulated with a variety of ingredients. With their neutral pH and the ability of enzymes to be readily broken down as part of an effluent stream, enzymatic products are the perfect candidates for environmentally conscious facilities. Because of this, it is important that the other ingredients in enzymatic cleaners are also biodegradable. There are a number of surfactants in enzymatic products that, while excellent from a soil removal perspective, have become globally unacceptable, such as nonylphenol ethoxylates (NPEs). This class of surfactants, and others like them, are not biodegradable and persist in the environment. With the large effluent stream that is part of every healthcare facility's instrument reprocessing, it is important to consider the effects on the environment of every product you select for use.
- Preservation: Enzymatic products should be adequately preserved (bacteriostatic). Since enzymes are organic molecules they can be subject to bacterial contamination. Data should be available from the manufacturer demonstrating that the product will not promote bacterial growth.
- Important considerations for safety: As is the case with any chemical or cleaning compound, enzymatic products must be



levels of foam for three different enzymatic cleaners in a shaker foam test.

handled appropriately and according to manufacturer's instructions to ensure the safety of healthcare workers. Allergic reactions can occur after repeated exposure to proteinbased materials such as pollen, dust and pet dander. Since enzymes are protein-based, repeated inhalation of dust and aerosols can result in allergy symptoms, so it is not recommended that enzymatic products be allowed to dry on surfaces. Also, they should not be used in spray applications where they could be aerosolized. Enzymatic cleaners should be thoroughly rinsed from instrument

surfaces and ideally should be part of a two-step process where a second non-enzymatic detergent is used as the second phase. Appropriate PPE (such as the protection already recommended for central service employees dealing with bodily fluids) should be worn.

Central service departments

CS departments typically use both manual and automated cleaning processes. One of the benefits of enzymes is that they work well with less mechanical action and can clean in hard-to-reach places such as lumens, spring-loaded joints and hard-to-remove sections. Enzymatic cleaners can also help to reduce the time required in sonic cleaning systems. The proper enzyme ingredients and surfactants can enhance the effectiveness of the cavitation action. Reducing the time and effort it takes to clean scopes, cameras and other complex equipment can add time to the day.

In order to achieve the most effective cleaning in automated systems, detergents used in washer-disinfectors should be evaluated for their ability to maximize the equipment's efficiency. Cleaning chemistries should be designed to work with the mechanical action of washer/disinfectors to optimize cleaning. Also, enzymatic cleaners used in high impingement systems should be low-foaming, since high-foaming products may lower water pressure within the washer and reduce spray arm rotation and water force against the load items, which could lead to a less effective cleaning process. An excess of foam also impedes the rinsing process. Not all enzymatic cleaners are designed to work for manual cleaning and automated cycles, so the foaming profile of enzymatic cleaners can vary widely.

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Gastroenterology labs

Enzymatic cleaners have an integral role in the processing and cleaning of endoscopes in the GI suite. The proper enzymatic solution will quickly and easily remove biological soils from an endoscope after a procedure. As is the case in the CS department, endoscopes must be thoroughly cleaned and dried before highlevel disinfection or sterilization can take place.

The use of an enzymatic product on endoscopes can begin at bedside immediately after the procedure is completed. Once it reaches the GI Lab, the endoscope is manually cleaned and immersed in the sink.

While good cleaning performance is a must, protecting the scope from chemical damage is just as important. When selectting an enzymatic cleaner for scope reprocessing, it's important to know your scopes' component materials and to ask for data from the enzymatic product manufacturer that discusses the product's protective abilities. Choosing the right enzymatic cleaner can increase the productivity in the GI space, and can protect the investment of expensive instruments and scopes.

The best knowledge yields the best results

Enzymatic cleaners are a necessary component in the surgical instrument cleaning process. When properly selected and used, they safely and thoroughly prepare expensive surgical instruments for the washing and disinfection phase of the reprocessing cycle. Now that you are armed with the facts about the nature and capabilities of enzymatic formulations, you can apply best practices based on professional guidance and gain the full benefits of a valuable reprocessing chemistry. HPN

C. Wayne Root, RN, is the Service Delivery Leader for the Central Sterile Reprocessing Department, St. Joseph Mercy Hospital, Ann Arbor, MI.

Nancy Kaiser is the Product Technologies Senior Manager at STERIS Corporation.

Christopher Antonucci is the Product Manager for Instrument Cleaning Chemistries at STERIS Corporation.

References:

ANSI/AAMI ST79:2006

AORN: 2008 Guidelines and Recommendations (PNDS:170,175) SGNA-Standards of Infection Control of Reprocessing Gastrointestinal Endoscopes-2008

IAHCSMM-Central Services Technical Manual-7th Edition, 2007.

For information from key professional organizations about enzymatic cleaners, see www. hpnonline.com, November 2008

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What, how and why: Enzymatic instrument cleaning products in healthcare environments

Circle the ONE correct answer:

1) In order to be highly effective for all surgical soils, an enzymatic cleaner formulation should have:

- a) Proteases and surfactants
- Proteases and lipases b)
- Surfactants and lipases c)
- Proteases, lipases and surfactants d)

2) What is the optimal water temperature range that allows an enzymatic cleaner to work effectively?

- a) 75-100°F
- b) 150-200°F
- c) 100-140°F
- d) 120-180°F

3) What factors impact the efficiencies of an enzymatic cleaner?

- Temperature
- b) Concentration
- Soil c)
- d) All of the above

4) Some enzymes found in multi-enzyme products, such as cellulases, are typically included in powdered laundry products to dissolve grass stains on cloth. a) True

- b) False
- 5) The most beneficial use of an enzymatic chemistry is a part of an overall platform providing instrument protection, cleaning efficacy and rinsibility.
 - True a)
 - False b)

6) Enzymes are: a) Part of a class of molecules called proteins

- b) Catalysts that speed the rate of reactions
- Effective at low concentrations c)
- d) All of the above

7) Surfactants are:

- a) Surface active agents
- b) Wetting and emulsifying agents
- A type of enzyme c)
- d) A and B

8) In order for enzymatic cleaning products to perform as intended:

- Certain ingredients should be listed on the a) label
- The product should be formulated to be b) effective
- c) Should not negatively impact automated washer efficiency
- d) B and C

9) Enzymatic cleaners are beneficial because:

- a) They can work at neutral pH
- b) The can reduce the need for mechanical action
- A and B c)
- d) They contain multiple enzymes

10) In order for enzymatic cleaners to be used safely they should:

- a) Not be allowed to dry on instruments
- Not be aerosolized b)
- Used with proper personal protective
- equipment
- d) All of the above

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What key professional organizations say about enzymatic cleaners:

he professional organizations have published their recommendations and insights into the use of enzymatic cleaners in healthcare facilities. Their recommendations are based on cleaning efficacy, instrument protection, safety, and patient outcomes.

AORN (Association of periOperative Registered Nurses) published the following recom-



mendations in its 2008 edition:

"Neutral detergents/enzymes with a pH of 7, that are low foaming and free-rinsing should be used for mechanical or manual cleaning of surgical instruments and equipment ... Neutral pH detergents work well used in combination with enzymatic solutions as part of a cleaning regimen." (PNDS: 170,175)

IAHCSMM (Association of Healthcare Central Services Materiel Management)



gives the following factors for the proper use of enzymatic product in their Central Service Technical Manual-Seventh Edition:

- 1. Water temperature in the decontamination area
- 2. Room temperature in the decontamination area
- 3. Useful life and stability of the product being considered
- 4. Expiration date of product
- 5. The material used to construct the device to be cleaned (material compatibility)
- 6. Whether the detergent (enzyme) is approved and registered with the Environmental Protection Agency (EPA)

SGNA (Societv of Gastroenterology



Nurses and Associates) published new guidelines in 2008 for the use of enzymatic cleaners on endoscopes in the GI Suites:

1. Medical grade, low foaming, neutral pH chemistry 2. Specially formulated bactericidal endoscope detergent

designed specifically to detach and destroy biofilm 3. An enzyme detergent designed for endoscopes

4. A detergent formulated to remove synthetic lipids 5. Free rinsing

AAMI (Association for the Advancement of Medical Instrumentation) published in 2006 their Comprehensive



guide to steam sterilization and sterility assurance in health care facilities. Within this text they outlined important considerations for cleaning products.

"When choosing cleaning agents for use in health care facilities, it is important to remember that the agent should be compatible with the medical device to be cleaned as well as with the materials used in the cleaning equipment itself. For example, the chemicals should not cause corrosion in ultrasonic cleaning equipment, washerdisinfectors, or washer-sterilizers; and they should not promote electrolytic action between the equipment and the medical devices being cleaned. In addition, any chemical should be easily removable from the medical device by rinsing with readily available water of defined properties so that the device does not retain residual chemicals in amounts that could be harmful to patients, damage the device itself, or create other hazardous situations. An ideal cleaning agent would

- 1. be nonabrasive
- 2. be low-foaming
- 3. be free-rinsing
- 4. be biodegradable
- 5. rapidly dissolve/disperse soil
- 6. be nontoxic
- 7. be efficacious on all types of clinical soil
- 8. have a long shelf life
- 9. be cost-effective

Rationale: Certain detergents can damage metal or other device materials."