Enzymatic Detergents play a useful role in Pre-Cleaning

Seeing is not believing when assessing the cleanliness of surgical instruments. Organic residue may be present but invisible to the naked eye, or hidden in the lumens and channels of complex instruments like endoscopes, yet instruments must be thoroughly cleaned before they are sterilized and reprocessed.

Cleaning is the process of removing all foreign material from instruments. In the surgical setting, this material is likely to include blood, tissue, mucous, and other body fluids. While cleaning may reduce the amount of bacteria on an instrument, it is not equivalent to disinfection or sterilization.

As the first step in the reprocessing cycle leading up to high level disinfection or sterilization, cleaning is usually performed with water and detergent or water and an enzymatic detergent. Thorough cleaning is crucial to the effectiveness of later steps in reprocessing. This seemingly simple step can be affected by factors such as:

- The complexity and configuration of the surgical device
- Loading patterns, load size and water pressure when using automatic washers
- Water hardness
- Detergents
- The type and amount of soil on the items being processed

**Characteristics of enzymes and enzymatic detergents**

Enzymatic detergents were developed to aid in the cleaning of endoscopes and other medical devices where organic material is difficult to remove by other methods. They are intended for use in soaking or pre-cleaning instruments as a first step in the disinfection or sterilization cycle. Enzymes have a variety of uses, but as catalysts in the cleaning process they were first introduced in laundry detergents in the 1960's. Enzymatic detergents were adapted for medical instrument cleaning more than a decade ago, and their use has become common practice in the United States in the last several years. The detergents are also used in veterinary and dental medicine.

**An enzymatic detergent typically consists of a detergent base with a neutral pH plus one or more enzymes and a surfactant (surface acting agent) that lowers the surface tension of the liquid so that it can penetrate deeper and prevent debris from being redeposited on the instrument during cleaning. The enzymes break down organic molecules into simpler compounds that are usually water-soluble and can be easily rinsed with water. Once the organic material is broken down, the detergent removes the dissolved particles from the instrument’s surface.**

Most enzymatic detergents sold today are in liquid concentrate form, although powders and tablets are also available. The concentrates are diluted with water and then used in manual soaking or dispensed in automated washing equipment, such as washer/sterilizers and washer/decontaminators, or endoscope reprocessors. Enzymatics can also be used in ultrasonic equipment.

Enzymes are proteins produced by living cells. They possess the ability to accelerate certain chemical reactions. As catalysts, they are extremely effective in speeding up chemical changes without being changed themselves in the process. These characteristics make them useful in instrument cleaning because in a matter of minutes they can loosen organic material such as dried blood.

Each enzyme consumes or attacks a particular substance when the chemical reaction takes place. The protease enzyme, for example, breaks down protein such as blood, mucous, faeces and albumin. Amylase catalyzes starch and lipase loosens and removes fatty deposits such as bone marrow and adipose tissue.

The quantity and quality of the enzymes in cleaning products varies. Some enzymatic detergents contain only one enzyme, while others have two, three, or four enzymes. Single-enzyme products typically utilize a proteolytic enzyme because most of the organic material found in general surgery, medical, veterinary and dental settings is proteinaceous. An enzymatic product designed for use in cleaning orthopaedic instruments might contain both a protein-attack enzyme and a lipase for breaking down fat. A detergent containing amylase and protease could be especially effective in cleaning instruments used in gastrointestinal procedures. The quality of a particular detergent depends on the type of surfactant it contains as well as the quality of the enzymes.

**Recommendations for Use**

The claims most frequently made for enzymatic detergents are that they quickly break down organic matter, reducing the need for lengthy manual scrubbing of instruments. In turn, employees face a lower risk from handling instruments and being exposed to blood and other bodily fluids. Another perceived benefit is that the detergents, which are biodegradable, can be used in...

Continued on pg. 2

Published by Safmed (Pty) Ltd.
July 1999
Glutaraldehyde has long been the chemical of choice for the disinfection of heat-labile instruments such as flexible endoscopes and as the first-choice "cold liquid sterilant" when such an approach is desired for surgical instruments. The accompanying table summarises the advantages and disadvantages of glutaraldehyde:

<table>
<thead>
<tr>
<th>ADVANTAGES</th>
<th>DISADVANTAGES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glutaraldehyde has been recognised as the ‘Gold standard’ for cold liquid sterilization and endoscope decontamination worldwide and as being a highly effective biocide</td>
<td>Toxicity to staff and compliance with Health &amp; Safety legislation is a big issue</td>
</tr>
<tr>
<td>Recommended as a cold liquid sterilant in all major infection guideline documents worldwide</td>
<td>Major investment in ventilation is required. Increasing restrictions on usage</td>
</tr>
<tr>
<td>Recommended by endoscope manufacturers and regarded as non damaging to instruments</td>
<td>Nurses forced to wear uncomfortable and restrictive protective clothing</td>
</tr>
<tr>
<td>Long-life formulations (14-28 days)</td>
<td>Nurses using employers</td>
</tr>
<tr>
<td></td>
<td>Poor mycobactericidal activity &amp; long sterilization times (users are often unaware) - slow turnaround, more instruments required</td>
</tr>
<tr>
<td></td>
<td>&quot;Fixes&quot; protein onto endoscopes - thorough pre-cleaning with enzymatic detergents is recommended - extra cost</td>
</tr>
</tbody>
</table>

Despite its obvious advantages, it can be seen from the table that glutaraldehyde is a hazardous substance known to be toxic, irritant and allergenic with occupational asthma being the principal concern. The safe use of the product should therefore be of primary concern to all healthcare workers using it.

**Standards and Guidelines**

In the USA, standards of care for the use of glutaraldehyde products are available from specialty organizations such as Society of Gastroenterology Nurses and Associates (SGNA) and Association of Operating Room Nurses (AORN), which have significant experience and interest in the safe and effective use of liquid chemical disinfectant/sterilants. Combining these standards with regulations from OSHA (Occupational Safety and Health Administration), FDA, state and local boards of health and guidelines from Association for Professionals in Infection Control & Epidemiology (APIC) and Joint Commission on Accreditation of Health care Organizations (JCAHO) provides the basis for individual departments and clinics to develop protocols, procedures and practices.

The country where glutaraldehyde is perceived as the greatest problem, and certainly the one with the most advanced legislation, is the UK where the current legal atmospheric level has been reduced from 0.2ppm to 0.05ppm in 1999. The way is being led by formal governmental legislation, in particular the COSHH (Control of Substances Hazardous to Health) regulations, extracts of which are shown below:

**COSHH Regulations for Hazardous Substances including glutaraldehyde**

1. Remove the hazardous substance by substituting a safer material or changing the process

When this is impractical exposure should be controlled by enclosing the process, using extraction and ventilation equipment, and adopting safer working and handling procedures. The container in which glutaraldehyde is stored and used should be large enough to completely submerge the object/instrument to undergo high level disinfection. It also should have a tight-fitting lid to contain the fumes and prevent spills. Many glutaraldehyde manufacturers will provide containers of various sizes made of the recommended materials to protect the instrument, personnel, and the product. Open containers of glutaraldehyde solution are not acceptable. Closed solution systems typical of many automated reproasers are ideal. A closed system also will help contain vapours which have the potential for respiratory irritation in health care workers.

2. Personal protective equipment

This may be used to achieve adequate control when other measures are not reasonably practical, or as addition to other measures to achieve adequate control and should include the following:

- Wear disposable waterproof aprons. These should be discarded if soiled with disinfectant.
- Use Nitrile gloves which are long enough to protect the forearms from splashes. These should be changed regularly because they absorb glutaraldehyde.
- Wear goggles to prevent conjunctival irritation and protect the wearer from splashes.
- Disposable charcoal impregnated face masks may reduce inhalation of vapour from disinfectants, but experience with them is not yet widespread.
- An approved vapour respirator should be available in case of spillage or other emergencies. It should be stored away from disinfectants as the charcoal adsorbs fumes and respirators should be replaced regularly.

3. Monitoring of Staff Exposure

Regular monitoring of the glutaraldehyde vapour levels should be performed. There are two ways to test staff exposure. One is to have the worker wear a dosimeter which is a passive monitoring unit that measures the amount of glutaraldehyde in the air for a specified time. The result will depend on how close the technician or nurse stands to the tank, what activity was performed (putting an instrument into the solution or removing it), the surface area of the solution in the tank, and the ventilation in the room. The other approach is to measure air levels using a portable unit, which depending on the number of departments using glutaraldehyde in the hospital may be a more cost effective alternative. The disadvantage of these units is that they require frequent and precise calibration. No matter what device is used for testing, an above normal reading requires immediate attention.

**Conclusion**

The use of glutaraldehyde has become fairly widespread in a hospitals over the years and in addition to its use in the Operating Theatre, departments such as Casualty, ICU and CCU use it routinely to reprocess such diverse items as laryngoscope blades, ultrasound probes and respiratory therapy equipment. Unless strict protocols are in place, a variety of containers, ventilation systems and protective clothing will typically be found. As a result of this, acknowledged concerns over glutaraldehyde’s health and safety profile have been raised.
Sa medial’s training programme for the CSSD worker has received wide support. The programme which consists of the following 9 modules has now been completed in many hospitals.

- Basic Microbiology
- Decontamination and Cleaning
- Sterile Packaging
- Steam Sterilization
- Steam Sterilization Practice
- Sterile Storage and Distribution
- Mechanical Monitoring and the Bowie-Dick Test
- Biological and Chemical Indicators
- Record Keeping

On completion of the course and after successfully passing a written examination based on the 9 modules, certificates are presented.

Pictured below are participants from St Augustine’s and Westville Hospital’s who were amongst the first to complete the course.

Enzymatic detergents are recommended for use by several professional associations, such as the Association of Operating Room Nurses (AORN), the Society of Gastroenterology Nurses and Associates, Inc. (SGNA), the American Society for Hospital Central Service Personnel (ASHCSP), and the Association for Professionals in Infection Control and Epidemiology, Inc. (APIC)

AORN’s Recommended Practices for the Care and Cleaning of Surgical Instruments and Powered Equipment, is designed to provide guidelines for perioperative nurses and it endorses enzymatic detergents. The section concerning initial decontamination following completion of an invasive procedure includes the following statement: “Pre-rinsing in an enzymatic detergent solution effectively removes all visible debris except ointment, thus proving to be an acceptable alternative to manual cleaning.” The AORN recommendations also state that an enzymatic soak solution “may be useful” for delicate instruments and other hard-to-clean instruments that are cleaned manually. While it is difficult to estimate how closely AORN recommendations are followed, they are often used in legal citations, and included as a criterion for accreditation for the Joint Commission for Accreditation of Healthcare Organizations (JCAHO).

SGNA has published a monograph entitled Standards for Infection control and Reprocessing of Flexible Gastrointestinal Endoscopes, which also recommends the use of enzymatic detergents. An enzymatic detergent solution on a cloth or sponge is used to wipe the insertion tube of the endoscope immediately after it is removed from the patient. The distal end of the endoscope is then placed in the solution and alternate suctioning of detergent solution and air follows. The guidelines then suggest that a fresh enzymatic solution be used in the mechanical cleaning of the endoscope.

The Training Manual for Central Service Technicians, published by the American Society for Hospital Central Service Personnel of the American Hospital Association, recommends that the first step in manual cleaning is to immerse instruments in a solution of water, detergent, and/or enzyme cleaner designed to remove blood. APIC guidelines state that “cleaning of endoscopes and accessories should be performed with non-abrasive, manufacturer-recommended enzymatic detergents for medical instruments promptly after use to prevent drying of secretions.”

Conclusion

Enzymatic detergents have earned a place in the healthcare setting for their ability to loosen and remove organic debris from surgical instruments. Effectiveness depends less on which enzymatic product is used than on whether it is properly used. The key to effectiveness of enzymatic detergents include soaking instruments for the correct amount of time and using the appropriate dilution.

References
2. Kneebler JA, Darling MH. Using an enzymatic detergent to pre-rinse instruments. AORN J. 1990;51:1326-1332
Steam Indicator Standards

There is a large variety of chemical indicators for steam cycles available on the market today and it is very important to realise when selecting an indicator for a particular application, that the performance characteristics of these indicators varies considerably. The International Standard entitled Sterilization of health care products - Chemical Indicators - ISO 11140-1 can be of great assistance in helping hospital personnel to select the correct indicator for a specific purpose. This standard classifies chemical indicators as follows:

**Class 1: Process indicators**
Process indicators are intended for use with individual units, (e.g. Packs, containers) to demonstrate that the unit has been exposed to the sterilization process and to distinguish between processed and unprocessed units. The endpoint indicating exposure to a steam sterilization process shall not occur until the indicator has been exposed to saturated steam for not less than 3 minutes at 121-124°C, or for 30 seconds at 134-137°C. (An example of a Class 1 indicator is the Propper Temptube™)

**Class 2: Indicators for use in specific tests**
These indicators are designed for use in specific test procedures as defined in relevant sterilizer/sterilization standards. (An example of a Class 2 indicator is a Bowie-Dick test)

**Class 3: Single parameter indicators**
As single parameter indicator shall be designed for one of the critical parameters of time, saturated steam and temperature and shall indicate exposure to a sterilization cycle at a stated value of the chosen parameter. (An example of a Class 3 indicator is the Propper Temptube™)

**Class 4: Multi-parameter indicators**
A multi-parameter indicator shall be designed for two or more of the critical parameters which affect the efficacy of the sterilization process to be monitored and shall indicate exposure to a sterilization cycle at stated values of the chosen parameters. Multi-parameter indicators shall undergo a clearly detectable change indicating exposure to the sterilization cycle at defined parameters within the relevant tolerances listed in Table 1. The defined parameters and the stated values at which the indicator reaches its endpoint shall be identified or coded on the indicator. (An example of a Class 4 indicator is the Browne™ MVI Steam Indicator strip)

**Class 5: Integrating indicators**
Integrating indicators are indicators designed to react to all critical parameters over a specified range of sterilization cycles. The exposure required to effect the change in the indicator shall be related to the inactivation of a theoretical micro-organism of stated D or z values. These values shall be not less than those specified in the appropriate parts of ISO 11138 for biological indicators for use in routine monitoring of the relevant sterilization process. The theoretical inactivation of the micro-organism shall be stated as the fractional reduction in the population, expressed as the log10. Integrating indicators shall undergo a clearly detectable change indicating exposure to a sterilization cycle at defined parameters within the relevant tolerances given in Table 1. The stated values shall be identified or coded on the product. (An example of a Class 5 indicator is the Verify™ Steam Integrator)

**Class 6: Emulating indicators (cycle verification indicators)**
Emulating indicators are indicators designed to react to all critical parameters over a specified range of sterilization cycles, for which the stated values are based on the settings of the selected sterilization cycles. Emulating indicators shall undergo a clearly detectable change indicating exposure to a sterilization cycle at defined parameters within the relevant tolerances given in Table 1. The stated values shall be identified or coded on the product. (An example of a Class 6 indicator is the Browne™ TST Control)

### Table 1: Tolerances and limiting values for response to critical parameters for Steam Indicators

<table>
<thead>
<tr>
<th>Indicator Class</th>
<th>Time (Minutes) Limiting Values</th>
<th>Temperature°C Limiting Values</th>
<th>Steam Saturation Limiting Values</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Lower</td>
<td>Upper</td>
<td>Lower</td>
</tr>
<tr>
<td>4</td>
<td>- 25 %</td>
<td>0 %</td>
<td>-2</td>
</tr>
<tr>
<td>5</td>
<td>- 15 %</td>
<td>0 %</td>
<td>-1</td>
</tr>
<tr>
<td>6</td>
<td>- 6 %</td>
<td>0 %</td>
<td>-1</td>
</tr>
</tbody>
</table>

The performance of a Class 4 (Multi-parameter) indicator with stated values : 3,5 minutes, 134°C should therefore be -:

To reach its endpoint, the time needed shall be at least 2,7 minutes (not more than 25 % below 3,5 minutes) with a temperature of 132°C (not more than 2°C below 134°C) and a dryness factor between 0,85 and 1,0

On the other hand the performance of a Class 6 (Cycle verification) indicator with stated values : 3,5 minutes, 134°C should be :-

To reach its endpoint, the time needed shall be at least 3,3 minutes (not more than 6 % below 3,5 minutes) with a temperature of 133°C (not more than 1°C below 134°C) and a dryness factor between 0,85 and 1,0