

# **Harness the Power of Nature for Improved Medical Device Cleaning**

## *Enzymes in Medical Detergents Overview*

### **What are enzymes?**

Enzymes are proteins that act as catalysts. This means that they speed up processes in every living organism. They are found everywhere, thousands of them exist within our bodies and there are even more in nature. In our bodies and those of animals, they play roles in many critical biological functions including cellular metabolism, detoxification of chemicals and digestion. Nature relies on enzymes to maintain natural carbon and nitrogen cycles necessary for life to exist and persist. With the aid of certain specific enzymes, reactions needed to breakdown organic molecules can occur in milliseconds. These types of reactions are occurring within us, all around us and they are critical to life.

### **Where are enzymes used today?**

For thousands of years, many civilizations have harnessed the power of enzymes in brewing, baking and making cheese. <sup>1</sup> While enzymes are used in many similar ways today, the science of enzymes has evolved tremendously creating opportunities for new “green and sustainable” applications in many industries. Enzymes are used to improve efficiency of a wide variety of industrial processes -- for example, in the manufacture of margarine, beer, yogurt, leather, textiles and ethanol. Enzymes are also routinely added to detergents to help remove stains from fabrics, caked on food from dirty dishes and patient soils from used surgical instruments including endoscopes.

### **Use of enzymes in medical device cleaning**

According to the latest estimate from the National Health Statics Reports an estimated 48.3 Million surgeries are performed per year in the US.<sup>2</sup> That estimate will only continue to climb as the population expands and ages and more people gain access to better healthcare. With an increase in the number of procedures comes an increase in the number and types of reusable medical devices, some are complex in design and often require enhanced cleaning technologies to reduce the infection risk. The cleaning step is the most critical step in the reprocessing cycle for removal of visible soils as well as obscured or hidden soils. Both the FDA and CDC guidelines <sup>3-4</sup> are emphatic that meticulous cleaning is critical prior to disinfection and/or sterilization. Improperly cleaned surgical instruments and complex reusable devices such as endoscopes pose an increased risk of healthcare acquired infections.<sup>5-6</sup> Enzymatic detergents designed specifically for cleaning reusable medical devices have been around for several decades and some studies have demonstrated improved performance over non-enzymatic detergents for cleaning soiled devices.<sup>7</sup> Enzymatic detergents are referenced in multiple industry standards such as AAMI ST79 as well as the aforementioned guidelines established by the FDA and the CDC. Properly formulated enzymatic detergents are used to aid the cleaning processes in pre-treatments, manual soaks, ultrasonic baths and automatic washer-disinfectors under neutral or mildly alkaline conditions.

### **Types of enzymes used in medical detergents**

The two main enzymes used to clean medical devices today are protease and lipase. Proteases are designed to breakdown protein rich soils like blood, while lipases target fatty soils like adipose tissue. Other enzymes that are traditionally used in medical device cleaning applications are amylases and cellulases, which breakdown starch and cellulosic polymers, respectively, facilitating their removal during cleaning. These target soils may be found in human waste such as feces. Combining multiple enzymes with a properly formulated detergent can be beneficial to

breakdown a variety of human soils and waste as well as invisible organic films that may build up over time due to ineffective cleaning of the internal lumens and channels of certain medical devices like endoscopes.

## Enzyme functionality

Enzymes are an important component of a good cleaning detergent and work in synergy with a good surfactant, or wetting agent, to aid in the complete removal of clinical soils from surgical instruments. Enzymatic detergents are most effective when used according to their instructions for use. Depending on the type of enzyme used, enzymatic detergents can breakdown soils under a wide range of temperatures. Further, enzymes intended for medical device cleaning can also function at different pH levels from neutral to alkaline conditions. Added to a well- formulated detergent, enzymes can enhance cleaning and safety and be used during pre-cleaning at “bedside” to automatic washing in a hospital’s sterile processing department. Enzyme producers work closely with detergent manufacturers to develop the optimal functionality for effectively cleaning medical devices. As with any detergent, it is important to follow the manufacturer’s labels and device instructions for use for optimized enzymatic cleaning performance.

## What’s new with Enzymes?

Enzymes have been used in medical device cleaning for decades and many of the enzymes that were around then are still being used today. However, advancements in technology has allowed enzyme manufacturers to develop newer and better molecules that are more robust, functional and compatible with chemistries that were previously detrimental to enzymes. The enzyme toolbox has expanded and today they demonstrate improved stability and functionality under a wide variety of conditions.

In summary, the natural power of enzymes has been used for thousands of years, and today the same power is being used for many modern applications. Their use in detergents for medical device reprocessing is effective when used according to manufacturer’s labeling, for enhancing the cleaning of contaminated reusable medical instruments including endoscopes, a critical step in device reprocessing. Enzymatic detergents perform well under a wide range of use conditions, and are compatible with delicate instruments such as flexible endoscopes.<sup>4</sup> Through the years, guidelines have routinely recommended their use and studies have demonstrated improved performance over non-enzymatic detergents for cleaning soiled devices. Recent advancements in the design of enzymes have also improved their formulation compatibility and application functionality.

[1] Fernandes, P. (2010). Enzymes in Food Processing: A Condensed Overview on Strategies for Better Biocatalysts. *Enzyme Research*, 2010, 1-19. doi:10.4061/2010/862537

[2] National Health Statics Reports February 28,2017 from <https://www.cdc.gov/nchs/data/nhsr/nhsr102.pdf> Accessed March 28, 2018.

[3] Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, 2015. Available from [https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm25\\_3010.pdf](https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm25_3010.pdf). Accessed October 26, 2015.

[4] Guideline for disinfection and sterilization in healthcare facilities, 2008. Available from: <https://www.cdc.gov/infectioncontrol/pdf/guidelines/disinfection-guidelines.pdf>. Accessed February 26, 2016.

[5] Alfa, M. J. (2013). Monitoring and improving the effectiveness of cleaning medical and surgical devices. *American Journal of Infection Control*, 41(5), S56-S59. doi: 10.1016/j.ajic.2012.12.006

[6] Top 10 Health Technology Hazards for 2018. Available from <https://www.ecri.org/Pages/2018-Hazards.aspx>. Accessed April 6, 2018.

[7] Merritt, K., Hitchins, V. M., & Brown, S. A. (2000). Safety and cleaning of medical materials and devices. *Journal of Biomedical Materials Research*, 53(2), 131-136. doi:10.1002/(sici)1097-4636(2000)53:23.0.co;2-i

