



Our Position

- Caustic cleaners are unnecessary for instrument processing and present significant hazards to health and safety
- Properly formulated pH neutral instrument chemistries with excellent surfactants and synergistic enzymes can offer a safe and proven alternative
- The need to provide validated cleaning protocols for reusable medical devices has become a focal point in medical device reprocessing.



Sustainability

- Meeting the needs of our current generation without impacting the needs of future generations to meet their own needs
- Social responsibility to protect the public from exposure to harm
- All manufacturers are obligated to design instrument chemistries to control measures which may lead to possible harm.

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Precautionary Principle

- Ethical responsibility to maintaining the integrity of natural systems
- Willingness to take action in advance of definitive scientific proof when a delay could prove costly to society and nature as well as selfish to future generations

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Breaking the Chain

- Cleaning, decontamination and subsequent sterilization are essential steps in breaking the chain of infection.

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Cleaning

- The removal, usually with detergent and water, of adherent visible soil such as blood, protein substances and other debris from the surfaces, crevices, serrations, joints and lumens of instruments, devices and equipment by a manual or mechanical process that prepares the items for safe handling and further decontamination.

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Ineffective Cleaning

- Can affect the ability of medical devices
 - To function properly
 - Decreases the useful life of the device
 - Increases costs for repair and replacement
 - Can interfere with the effectiveness of subsequent sterilization or disinfection
 - Increases the risk of nosocomial infection

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Green Chemistry

- Chemical products and processes designed to reduce or eliminate hazardous substances
- Pollution prevention focus of EPA's Green Chemistry program

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Caustic Cleaners

- Alkaline detergents followed by acid neutralizers
- Present hazards to waste water stream
- Cause pitting and corrosion of surgical devices
- May result in safety issues for patients and staff

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Warning

The use of elevated temperatures in a cleaning process will cause denaturation and precipitation of soil components (blood) and make them more difficult to remove.

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Ideal Cleaning Agents

- Non-corrosive
- Free-rinsing
- Non-abrasive
- Low-foaming
- Biodegradable
- Environmentally Friendly
- Nontoxic in specified use dilution
- Provide for rapid soil dispersion or suspension
- May be used in all water types

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Cleaning Reusable Devices

- The critical first step in the decontamination process
- Multi-step process including manual and automated cleaning
- Followed by a thorough rinse with high purity water
 - Manual cleaning dependent on individual's performance. Mechanical reproducible.

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Validation

- The FDA places primary responsibility for developing and validating methods for effective processing of the medical device on the manufacturer of the device.
- Device manufacturers must provide procedures that must be easily replicated and verified by users

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The Validation

- Enzymatic detergents are often recommended for cleaning reusable devices.
 - Yet, there was little data to confirm the efficacy of enzymatic detergents for effective soil removal from patient-used medical devices
- Validation: Simulated-use evaluation of enzymatic cleaning
 - Evaluated static soak, manual cleaning, automated cleaning, and the recommended process
 - Inoculated devices
 - Organic soil reduction
 - Bioburden reduction

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Validation of Process

- Pre-cleaning using a pH neutral multi-enzymatic foam
- Brief rinse with tap water
- Ultra sonic cleaning with pH neutral detergent
- Manual cleaning with pH neutral multi-enzymatic cleaner
- Final rinse with tap water

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Results

- Hemostats soiled with ATS and microorganisms processed by the manufacturer's products and method resulted in a $\geq 6 \text{ Log}_{10}$ reduction bioburden and $> 99.9\%$ reduction in organic material post processing.
- Conclusion
 - The protocol of cleaning that is recommended by the manufacturer provides efficient cleaning of medical devices by providing soil and bioburden reduction.

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The pH Effect

- To determine if an increase in pH (alkalinity level) will improve or change the outcome of the cleaning protocol
- Two parallel studies were conducted of the entire cleaning protocol
 - One using neutral pH detergent
 - One using the same ingredients but with a pH of 9 (alkaline)

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pH Effect Results

- There was no significant difference in outcome between the pH neutral and the alkaline detergents
- In fact, there was a slight improvement in efficacy with the pH neutral detergent in replicate studies.

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Why Use Enzymatic Cleaners?

- Each enzyme is a catalyst working on a particular substrate much as a lock and key. If one enzyme is used only one type of organic soil will be broken down.
 - Protease breaks down protein
 - Lipase breaks down lipids (fats).
 - Amylase breaks down starch and carbohydrates.
- Multiple enzymes are needed to attack organic soils, so that they may be washed away.
- Hot water is not recommended nor needed.

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Why are Detergents Needed?

- Detergents are required for a thorough cleaning and removal of organic and inorganic soils, detergent residue, including enzymes.
- They may be used in hot water wash cycles for thermal disinfection.
- Detergents with chelating and sequestering agents are required for removal of salts, minerals and other hard water ions.
- In automated systems, when filtered, deionized or RO water systems are used lower concentrations of detergents may be used.

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What Instrument Manufacturers Say

- Chemicals used in cleaning and decontamination processes should be able to remove the type of soil found on the item while, at the same time, preserving the integrity of the item. Such cleaning agents should have the following properties:
 - Ability to remove organic and inorganic soil.
 - Ability to prevent deposits from hard water ions.
 - Low foaming.
 - Free rinsing.
 - Neutral pH (range 7-8)
 - Very acid or alkaline solutions can damage the inert layer that keeps stainless steel instruments from corroding.
 - Anodized aluminum containers require pH neutral products for decontamination and to maintain their corrosion resistance and useful life.

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Why Green Products?

- Environmentally friendly products are safe for the patient, staff, and the community.
- Color, dye, fragrance mask the degradation of the product (fading, sediment, mold!) and the odor of denatured enzymes.
- Most water systems in each of our cities limit the level of alkalinity in the water supply to a pH of 8.5, yet the alkaline detergents used may reach a pH of 14, the highest level possible and are dumped in our water supply, destroy medical devices, and if used on patients without rinsing, will cause injury or death.

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Summary

- Medical devices are critical for patient care.
- No instrument company recommends caustic detergents, because of the potential damage to the device.
- Breaking the myth means that there are instrument chemistries that are pH neutral, validated in independent studies, that are environmentally friendly, safe and effective, and demonstrate efficacy and sustainability.