HEALTHCARE PURCHASING NEWS

September 2021

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LEARNING OBJECTIVES

1. *List the types of soils found in endoscope procedures*
2. *Identify the key properties of cleaning chemistries effective against endoscopic soils*
3. *Create a checklist for evaluating endoscopy cleaning chemistries*

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SELF-STUDY SERIES

The perfect solution

Understanding, assessing and selecting endoscope cleaning chemistries

by Ann Kneipp and Nancy Kaiser

Endoscope reprocessing is time-consuming and complex, and it involves a two-step process. It begins with thorough cleaning – removing soil from a contaminated reusable device – and is followed by a disinfection or sterilization process. While there are a variety of guidelines and recommendations that address the importance of cleaning, they all say essentially the same thing: if it isn't clean, it cannot be properly disinfected or sterilized.

The right cleaning chemistry is critical for successful endoscope cleaning. However, not all chemistries are equal. Some formulations can leave residual soils, some can damage endoscope component materials, and some require more scrubbing, which can cause scratches and other damage. Soiled and damaged surfaces can harbor microorganisms and promote biofilm, which in turn prevents proper rinsing of the cleaning chemistry and ultimately reduces the effectiveness of disinfection or sterilization processes. With the safety of patients riding on thorough scope cleaning, how do you determine the right cleaning chemistry for your endoscopy practice?

Types of endoscopy soils

To determine the most appropriate cleaning chemistry for endoscope reprocessing, we must understand the procedures being performed and the types of soils that may be present after these procedures. Soils found on endoscopic devices come from a variety of sources.

For many flexible endoscopes, the most common source is the gastrointestinal (GI) tract. For example, patients prepare for endoscopy by taking "flush cocktails" to rid the tract of as much "debris" as possible and allow for clear viewing. These products leave residuals such as propylene glycol and sodium phosphate behind that can deposit on endoscopes. In cases where patient prep was incomplete or prep was not performed at all (as in emergency procedures), the fecal matter in the tract includes numerous types of soil, including bile, bilirubin (broken down red blood cells), mucus, undigested food and large amounts of bacteria. If polyps were removed, whole blood and membrane tissue may also be present.

Substances introduced during the procedure will also deposit on endoscopes and require removal. For example, petroleum jelly is often applied as a lubricant for patient comfort, and contrast dyes are instilled in the GI tract during chromoendoscopy to help identify suspect tissues. The practice of using simethicone (the antifoaming agent found in gas relief products) to reduce the amount and size of mucus bubbles and improve visualization has created a new cleaning challenge. Simethicone is especially hard to remove because it's not soluble in water or alcohol.

To understand how to remove various endoscopic soils, we need to categorize them into two general categories: *organic* and *inorganic*. Organic soils include protein, lipids/fats and carbohydrates.

Proteins are found in every type of tissue and fluid in the human body, so they are present on endoscopes after every type of procedure. Proteins are large, insoluble molecules with extremely complex multi-layered structures. These structures allow the molecules to function and protect them from breaking down, which makes proteins especially hard to remove.

Lipids are fatty, waxy and oily compounds that the body uses to build cell membranes and store energy. By their nature they are insoluble in water. The saturated and unsaturated fats present in the GI tract occur naturally in patients' bodies and are also introduced through their diets. Synthetic lipids (i.e., olestra) used as fat substitutes in "light" foods may also be deposited on endoscopes during lower GI procedures. Synthetic lipids have a larger molecular structure than natural lipids and are harder to clean.

Carbohydrates are starches and sugars, which are used by the body for energy. They consist of ringed structures in single and multiple groupings. Compared to proteins and lipids, carbohydrates are relatively easy to clean since they are somewhat water soluble.

Inorganic soils related to endoscopy include minerals introduced in saline and other flushing solutions, hard water contaminants such as calcium carbonate that may be in the water used to clean devices and metals like copper and iron (including rust).

Getting it all off

The first general rule for effective soil removal and cleaning is to preclean the devices *quickly* and *promptly*; quickly because soil is easier to remove while it's fresh and before it is allowed to dry on device surfaces, and promptly because processing delays can promote the proliferation of biofilms in moist, soiled channels. Biofilms are complex communities of microorganisms that stick to each other and to surfaces. The biofilm is covered in a slimy extracellular layer (matrix) that acts like glue, making its removal extremely difficult, especially with traditional cleaning chemistries. Biofilms can form very quickly, and once they do, additional cleaning steps with specialized products will be needed to remove them.

For any type of soil, thorough cleaning requires a combination of soil breakdown and physical removal. So how do chemicals accomplish these functions?

Removal

The term "removal" is often defined as mechanical actions (i.e., brushing or wiping) used during cleaning. However, cleaning chemistries also remove soils. They contain ingredients called *surface active agents* (surfactants) that function in several different ways. Surfactants provide wetting, suspending (emulsifying), solubilizing and anti-redeposition functions. They have a special structure with a hydrophilic (water-attracting) portion and a hydrophobic (water-repelling) portion, which allows them to line up at air/water and liquid/solid interfaces to perform their function.

Water does not wet surfaces well because of its surface tension. By lining

up at the interface where the water meets the air, a surfactant lowers this surface tension, allowing the water to sheet over surfaces and flow into tight spaces like the narrow channels of endoscopes. Once the cleaning solution effectively wets all surfaces, surfactants then line up at the interface between the soil and the cleaning solution to suspend soils so they can be rinsed away. Some surfactants are also able to pull soils completely into solution. Surfactants that provide effective suspension and solubilization will also prevent soils that have already been removed from redepositing on other endoscope surfaces as the scope is being rinsed.

However, detergents with poorly formulated surfactant systems can compromise cleaning, especially in automated endoscope reprocessors (AERs). For example, a cleaning chemistry that foams too much can cause the recirculating pump to cavitate (create vapor bubbles), which lowers the system pressure and reduces overall cleaning effectiveness. Foam bubbles also introduce air into endoscope channels, which limits the cleaning solution's contact with the channel walls. Excess foaming can also interfere with rinsing and can require more flushing and time to adequately remove all detergent residue.

Breakdown

In addition to removing soils, cleaning chemistries help break soils down. They break large, water insoluble molecules such as proteins and lipids apart into smaller, more water-soluble pieces. Breakdown occurs because of *hydrolysis*, *sequestration/chelation* and *surfactancy*.

Enzymatic cleaners break down tough soils with protease enzymes and the enzymatic hydrolysis process. Protease enzymes only break down proteins. Hydrolysis uses water to break molecules apart into smaller, more soluble pieces. Enzymes speed up the hydrolysis action.

Enzymes are proteins themselves. They function by holding the protein soil and water near each other to make them interact faster and more easily. The protease enzymes are not consumed by the reaction and will continue to work on protein soil as long as it is present on the dirty endoscope. This is especially helpful for the manual endoscope cleaning process because enzymes help remove protein soils in areas of the devices (such as lumens and channels) that are difficult to reach and where mechanical cleaning action is minimal.

The activity and efficacy of all enzymatic products also increases with temperature, but only to a certain point. Temperatures above 60°C (140°F) will start to denature the enzyme and prevent it from working. When enzymes denature, they start to unfold and lose their ability to speed the hydrolysis reaction.

Alkaline hydrolysis

Hydrolysis can also be driven by alkalinity (the capacity of water to resist acidification). The reaction in alkaline hydrolysis is slightly slower, and it is effective against both protein and lipid soils. However, alkaline hydrolysis is more aggressive – it does not discriminate between soils and device surfaces, and this can lead to potential material incompatibility issues and device damage. A controlled amount of alkalinity can help solubilize lipids and remove them.

Chelation

Sequestering/chelating ingredients can be beneficial to the cleaning process. Because of their ability to bind minerals and metals such as calcium, magnesium, iron, copper and zinc, chelants can control the hardness of tap water used for the

Self-Study Test Answers: 1. C, 2. D, 3. D, 4. C, 5. B, 6. A, 7. B, 8. D, 9. B, 10. B

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cleaning solution and thereby help the cleaning chemistry work better. Fats/lipids tend to interact with these hard water elements and become more rigid and harder to clean. Chelants also pull away ions that stabilize protein and lipid structures, allowing those soils to then be broken down and cleaned away more readily.

Sequestrants keep soils suspended in solution and prevent them from redepositing on devices. They also dissolve inorganic soils like patient preparation products and procedural flushing solutions.

It's important to note that while mild sequestrants/chelants (i.e., citric acid) are beneficial to endoscope reprocessing, strong versions of these ingredients are not compatible with enzymes. Including strong chelants like EDTA in a formulation will degrade enzymes and render them ineffective after only a short shelf-life.

Surfactancy is also involved in soil breakdown and soil removal, particularly for fatty and lipid soils. Surfactants can penetrate lipid soils and emulsify or solubilize them, which breaks them down just as well, if not better than other mechanisms, including enzymes.

Checklist for choosing the right formulation

Step One: assemble the team

Endoscopy managers should work with material management, infection prevention and reprocessing professionals at their facility to assess and select the optimal cleaning chemistries for their devices. Each of these experts will have knowledge that contributes to an informed decision.

Step Two: research the IFU

Access all endoscope manufacturers' instructions for use. Device manufacturers typically test a variety of cleaning chemistries to ensure device material compatibility and efficacy with the cleaning procedure they recommend for their device. Endoscope manufacturers most often recommend detergents and/or enzymatic cleaners that have *neutral pH* and are *low-foaming* and *free-rinsing*. These same recommendations are supported by industry standards and guidance.

Cleaning chemistry labeling offers a wealth of information as well. Information about the formulation helps with determining whether a cleaning chemistry will be effective and appropriate. For example, not all detergents contain enzymes, but a properly formulated enzymatic product includes both a detergent and enzyme(s). So, even if soil conditions don't require the enzyme, the formula's detergent will clean effectively. The choice is not detergent *or* enzyme, but a combination of ingredients that will result in optimal cleaning outcomes for all the endoscopes and accessories.

Step Three: list all anticipated procedures

The next step is to identify the types of procedures your endoscopes perform and the soils from those procedures. Remember to also consider the procedures that may be performed in the future as the facility grows and changes. A cleaning chemistry formulated for a wide variety of soils will help accommodate future procedural expansion.

Step Four: investigate your water

Water hardness can impact the effectiveness of a cleaning chemistry. Consider testing facility/department water quality to determine if water treatment is necessary to assure optimal cleaning.

Step Five: audit each chemistry's test data and value

Evaluate the performance data and overall value of each cleaning chemistry formulation being considered. Evaluation criteria for a cleaning chemistry should include:

- Verification of neutral pH
- Verification that the chemistry is low-foaming and free rinsing
- Proven effective performance against hard-to-clean soils such as lipids and proteins
- Demonstrated compatibility with device materials
- Ability to protect devices from corrosion during reprocessing

Cost is an important component of any product evaluation, but value is the ultimate indicator. Remember that a cheaper cleaning chemistry may not always be the most cost-effective choice in the long run. Be sure to consider:

- The cost of instrument repairs due to poor chemistry performance
- The differences in chemistry dosing volumes (concentrations)
- The cost (in staff time, supplies and postponed procedures) of recleaning because of poorly performing chemistries

Patient safety above all

A facility's choice of endoscope cleaning chemistry has implications beyond the department itself. Thoughtfully selecting a well-formulated, high-quality cleaning chemistry can certainly help improve the effectiveness and efficiency of the endoscope reprocessing function. But it also has the potential to enhance that department's reputation for delivering consistent, reliable cleaning outcomes that support patient safety initiatives. Considering that these complex reusable medical devices pose a serious infection risk if improper cleaning leads to incomplete disinfection or sterilization, the consequences could be dire for patients and the facility both. Keeping an eye on this bigger picture will lead to the optimal cleaning chemistry solution. **HPN**

Ann Kneipp is a senior scientist II in Research & Development for STERIS Corporation, based in St. Louis, Missouri. She has over 20 years of product formulation experience and holds 13 patents for healthcare consumer goods and instrument cleaning chemistries for surgical and endoscopic devices. Kneipp is a member of the International Association of Healthcare Central Service Materiel Management (IAHCSMM).

Nancy Kaiser is the scientific director for STERIS Corporation in St. Louis, Missouri with extensive expertise in formulation. She has more than 30 years of experience in developing healthcare products and holds more than 20 patents (with additional patents pending) in hard surface cleaners, instrument cleaning chemistries, disinfectants, antimicrobial skin care, and wound management products. She has also written numerous published articles and book chapters on these subjects. Kaiser is a member of the Association for the Advancement of Medical Instrumentation (AAMI) and sits on several AAMI committees. She holds a degree in chemistry from Washington University.

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CONTINUING EDUCATION TEST • SEPTEMBER 2021

The perfect solution

Understanding, assessing and selecting endoscope cleaning chemistries

Circle the one correct answer:

1. **What are endoscopic soils composed of?**
   A. Only organic substances
   B. Only inorganic substances
   C. Both organic and inorganic substances
   D. None of the above

2. **Where do endoscopic soils come from?**
   A. The patient's body
   B. Patient preparation and comfort products
   C. Procedural fluids
   D. All of the above

3. **Which are difficult to clean from endoscopes?**
   A. Proteins
   B. Fats, lipids, and synthetic lipids
   C. Biofilms
   D. All of the above

4. **Which of the following are cleaning chemistry mechanisms?**
   A. Insolubilation and deposition
   B. Scrapping and isolation
   C. Removal and breakdown
   D. Acidification and ionization

5. **How do enzymes aid in the cleaning process?**
   A. Slow soil breakdown
   B. Break down large protein molecules into smaller, more soluble ones
   C. Suspend soils in the solution
   D. Tie up metal ions

6. **Which formulation ingredient helps water to 'wet' surfaces?**
   A. Surfactants
   B. Enzymes
   C. Sequestrants/chelants
   D. Alkalinity

7. **What cleaning chemistry function keeps soil from sticking back onto a device?**
   A. Free-rinsing
   B. Anti-redeposition
   C. Chelation
   D. Emulsification

8. **Why is foam detrimental to the cleaning process?**
   A. It is more difficult to rinse thoroughly
   B. The bubbles can inhibit the cleaning solution from flowing through narrow channels
   C. The bubbles can prevent the cleaning solution from effectively contacting the device surfaces
   D. All of the above

9. **What can happen when soils and moisture remain within endoscope channels?**
   A. Nothing – it rinses out
   B. Biofilm develops
   C. Slippery channels
   D. Pressure differentials

10. **Scope manufacturers often state that endoscope cleaning chemistries should be acidic, low-foaming and free-rinsing.**
    A. True
    B. False

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