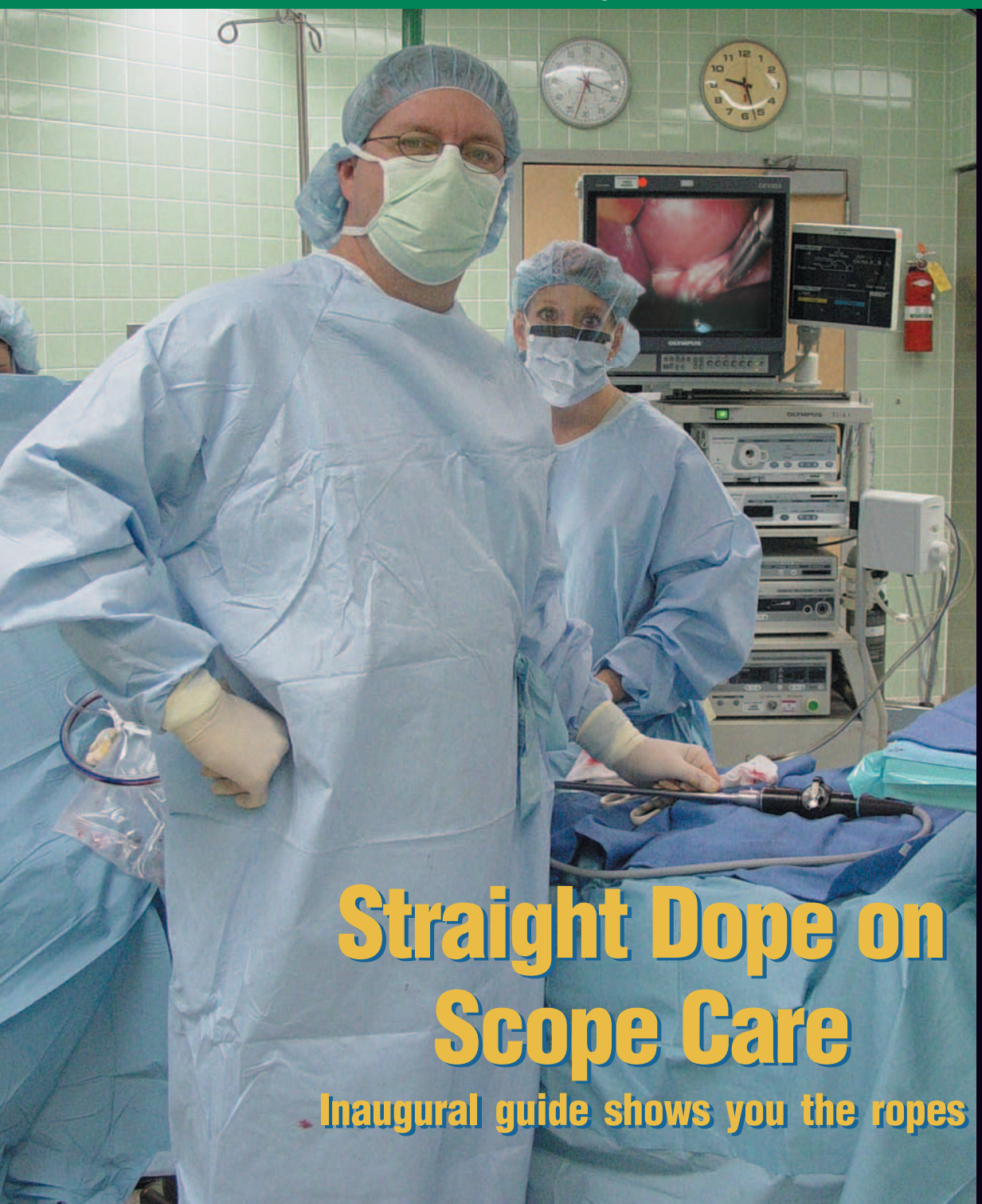
November 2005 • Vol. 29 No. 11

HEALTHCARE Purchasing NEWS

The market's first choice for business news and analysis

www.hpnonline.com



Straight Dope on Scope Care

Inaugural guide shows you the ropes

INSIDE...

Beyond Cleaning

Reprocessing flexible GI endoscopes successfully

- Is there really "sterile dirt"?
- A look inside a flexible endoscope
- Working with your AER manufacturer
- Water quality- a critical component

Scope Cleaning Guide

Because of a growing number of patient infections and injuries that have been linked to poorly, if not improperly, cleaned and cared for endoscopes, *Healthcare Purchasing News* decided to launch an annual guide to educate and reinforce proper cleaning, care and handling of these expensive devices. *HPN* enlisted experts in the manufacturing and reprocessing communities to offer advice and wisdom that should prove useful and valuable to our readers who are dedicated to delivering high-quality healthcare.

Beyond cleaning

Reprocessing flexible GI endoscopes successfully

by Bradley Catalone, Ph.D. and George Koos

Today, it is hard to imagine that anyone remotely associated with the gastrointestinal (GI) department has not heard of the risks and problems associated with improper or inadequate reprocessing of flexible endoscopy equipment.

A flexible endoscope, as with any medical instrumentation, cannot be high-level disinfected or sterilized without first being meticulously cleaned. Taking shortcuts in cleaning with the idea that high-level disinfection or sterilization will still render the scope safe for patients is an approach guaranteed to put patients at risk. The "Sterile Dirt" theory just doesn't cut it. There are several published examples of patient infections resulting from failure to properly clean an endoscope[1,2]. Manufacturer's guidelines for the cleaning of flexible endoscopes are well documented and should always be followed. Although cleaning is a major factor in rendering flexible endoscopes safe for reuse, there are other factors that could affect the successful disinfection or sterilization throughout the rest of the process. These factors are easy to maintain and monitor without further time constraints, but can be detrimental to the process if overlooked.

First, it is critically important to understand your equipment and how it is designed to function. This will allow your facility to best utilize the technology and be the most productive, while also minimizing damage, costly handling mistakes and the risk of cross contamination. There have been a number of reprocessing errors publicized in the popular press that have been attributed solely to not knowing specific functions, attributes or designs of endoscopes and associated equipment[3,4]. It is important that the staff is trained thoroughly by the manufacturer of each specific piece of equipment. More times than not, staff will ask questions of sales representatives regarding processes involving other companies' equipment. Only the manufacturer of the equipment should answer questions about its equipment.

Although flexible scope sales representatives are knowledgeable about the entire process of using the scope in the procedure through successful reprocessing, they are unable to answer questions regarding other manufacturer's automated endoscope reprocessors (AERs). Each AER manufacturer is required to validate its equipment and connections for use with each compatible endoscope. These AER manufacturers will have specific instructions for use, which may vary with each endoscope model. Not all flexible endoscopes may be compatible or validated for use in all AERs. Ask the manufacturer of your AER for an in-service to understand your equipment.

Secondly, only use validated connectors supplied by the AER manufacturer for each model of endoscope. Connections are vital to the disinfection or sterilization process in AERs. Each AER works with different pressures and designs, which in turn require specific connectors for specific scopes. Flexible endoscopes are complex devices comprising long, narrow lumens and bifurcations. The slightest difference in these channels may require different connections as determined and validated by the AER manufacturer. Endoscopes in the same series from the same manufacturer may have different channels and options that also require different connectors. When purchasing a new scope always contact your AER manufacturer for the right connectors and training. Once you have the right connectors, they must be maintained and cannot be modified. Do not allow staff to repair or replace parts of these connectors without specific authorization and instructions from the AER manufacturer. Contact your AER manufacturer with a list of your scopes to ensure you are using the proper connectors.

Next, have your equipment serviced regularly. If the endoscope has been thoroughly cleaned and properly connected with the AER manufacturer's validated connector, but the AER itself is not working according to specification, there again is a risk to the process. Flexible endoscopy equipment and AERs should be serviced and maintained according to the manufacturer's specifications. Many facilities maintain equipment with internal personnel, and these resources should be trained and have the proper instructions for the preventive maintenance and service of the equipment. Equipment may appear to be in working order, but only the proper upkeep can ensure the systems are working as intended. The repair and service of associated equipment is vital to ensuring the proper functionality of the scope. Proper maintenance also helps ensure patient safety by identifying physical damage that may reduce the effectiveness of reprocessing. Make sure your equipment and scopes are in good working order and contact the manufacturer for information as needed.

Water quality, specifically the AER incoming feed water and final rinse water, is a critical component of any successful endoscope reprocessing program. Numerous reports of nosocomial infections and pseudoinfections linked to AER rinse water clearly demonstrate the importance of water quality[2,5].

Here are some suggestions on how to maintain acceptable water quality:

- Check with the AER manufacturer to determine the specific requirements for the quality of the incoming feed water. Oftentimes, prefiltration systems are required to reduce the bioburden of the incoming feed water. Prefiltration will improve the quality of the water used to reprocess the endoscope, and also reduce contaminates that enter the AER internal tubing and reservoirs.
- Understand that the quality of the incoming feed water, especially for those facilities that do not centrally treat their incoming water, may change seasonally. As a result, the useful life of water filters may vary throughout the year.
- Maintain acceptable water quality by using the AER manufacturer's recommended filters and replacement frequency. Not all filters are manufactured to the same specification nor are they appropriate for use with an AER water treatment system.
- Implement a quality control program to routinely sample the final rinse water. Although routine sampling currently is not endorsed by any of the major professional societies or government agencies, documented patient infections and pseudoinfections due to contaminated water provide a strong rationale for this recommendation[5]. The wrong time to discover there is a water quality issue is after a patient infection.

Finally, proper drying and storage of flexible endoscopes reduces the risk of nosocomial infections. The multi-society guideline for reprocessing flexible GI endoscopes categorizes the final drying steps, including a flush with 70 percent to 90 percent ethyl or isopropyl alcohol followed by forced air, according to the guideline's strongest recommendation (Category IA: strongly recommended for implementation and strongly supported by well-designed

experimental, clinical or epidemiologic studies)[6]. In contrast, there currently is no recommendation for maximum storage time of properly reprocessed endoscopes. Some professional societies, including the Association of periOperative Registered Nurses (AORN), recommend that endoscopes be reprocessed immediately before use[7]. However, many facilities do not adhere to this recommended practice because the clinical benefits are not well established and the resources required are significant. In addition, very few studies have been published evaluating the safety of storing endoscopes for prolonged periods.

A primary reason for the lack of a consensus recommendation regarding endoscope storage is that the ability to maintain an endoscope in a patient-ready state during storage is highly dependent upon environmental factors that are unique to each facility. For example, the ambient air temperature and humidity, the number of air room changes per hour, and the general cleanliness of the endoscope storage area and cabinet are important variables that are related to the risk of endoscope contamination during storage.

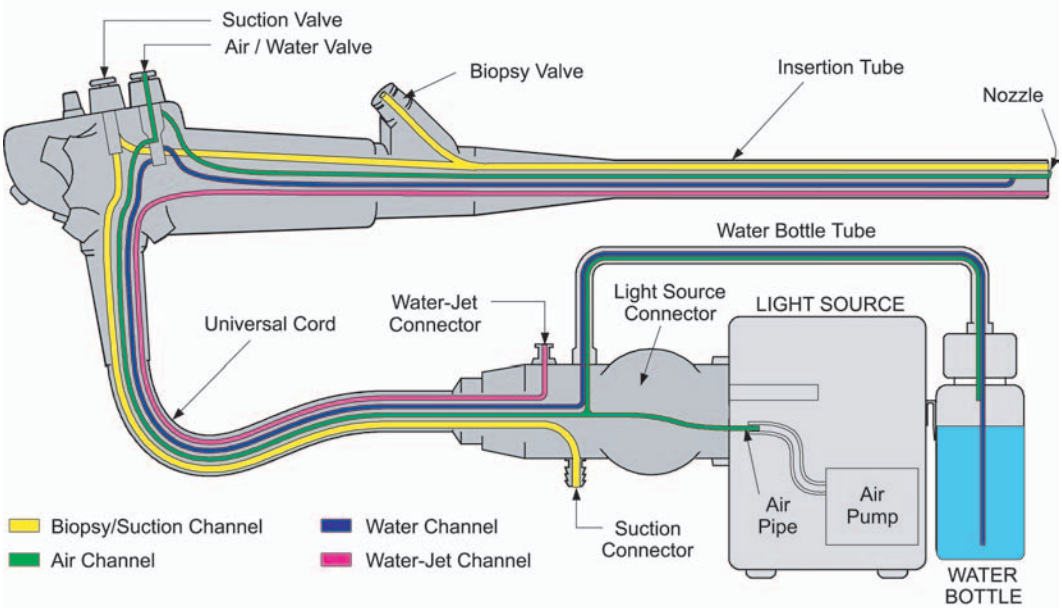
Everyone understands the importance of thorough cleaning, and hopefully the need to understand all the factors that contribute to safe and effective reprocessing. Healthcare facilities make great investments in areas like the GI department to create medical miracles every day utilizing advanced technologies and innovative procedures…don't risk patient safety by not having all the information. Utilize your equipment manufacturer's resources to train staff and optimize the performance and safety of your equipment. **HPN**

1. Alvarado CJ, and Reichelderfer M. APIC guideline for infection prevention and control in flexible endoscopy. *Am J Infect Control* 2000, 28: 138-55.
2. Mehta, AC, Prakash, UBS, Garland R, Haponik E, Moses L, Schaffner W, and G Silvestri. American College of Chest Physicians and American Association for Bronchoscopy consensus statement: prevention of flexible bronchoscopy-associated infections. *Chest* 2005; 128: 1742-1755.
3. Glionna, JM. Unsterile devices prompt warnings: use of dirty endoscopes in colon and throat exams can pass along infections activists say. *The Los Angeles Times*, Los Angeles, CA, Feb 13, 2003, p B1.
4. Fahy, J, and Spice B. Monroeville hospital urges 200 colonoscopy patients to get checked for hepatitis, HIV. *The Pittsburgh Post-Gazette*, Pittsburgh, PA, March 31, 2005.
5. Muscarella, LF. Application of environmental sampling to flexible endoscope reprocessing: the importance of monitoring the rinse water. *Infect Control Hosp Epidemiol.* 2002; 23(5): 285-289.
6. Multi-society guideline for reprocessing flexible gastrointestinal endoscopes. *Gastrointest Endosc* 2003; 58(1): 1-8.
7. Recommended practices for cleaning and processing endoscopes and endoscope accessories. 2005. Standards, Recommended Practices, and Guidelines. Denver: Association of periOperative Registered Nurses, 2005: 341-346.

Bradley Catalone, Ph.D., MBA, is senior manager of infection control for the Medical Systems Group of Olympus America. Prior to joining Olympus, Catalone worked in the pharmaceutical industry. You can reach Catalone via e-mail at bradley.catalone@olympus.com.

George Koos is the senior product manager for cleaning, disinfection and sterilization for the Medical Systems Group of Olympus America. He has specialized in infection prevention product lines for the last nine years, serving in various medical sales and marketing roles. You can reach Koos via e-mail at george.koos@olympus.com.

A look Inside the Common Olympus Flexible Endoscope



A. Flexible endoscopes are complex devices, many consisting of long narrow lumens with multiple bifurcations as shown above.
B. All channels of a scope must be reprocessed whether utilized during the procedure or not.
C. Due to the complexity of the channel structure of flexible endoscopes only the Automated Endoscope Reprocessor manufacturers connectors can be used with their systems.

Reprinted from Healthcare Purchasing News