

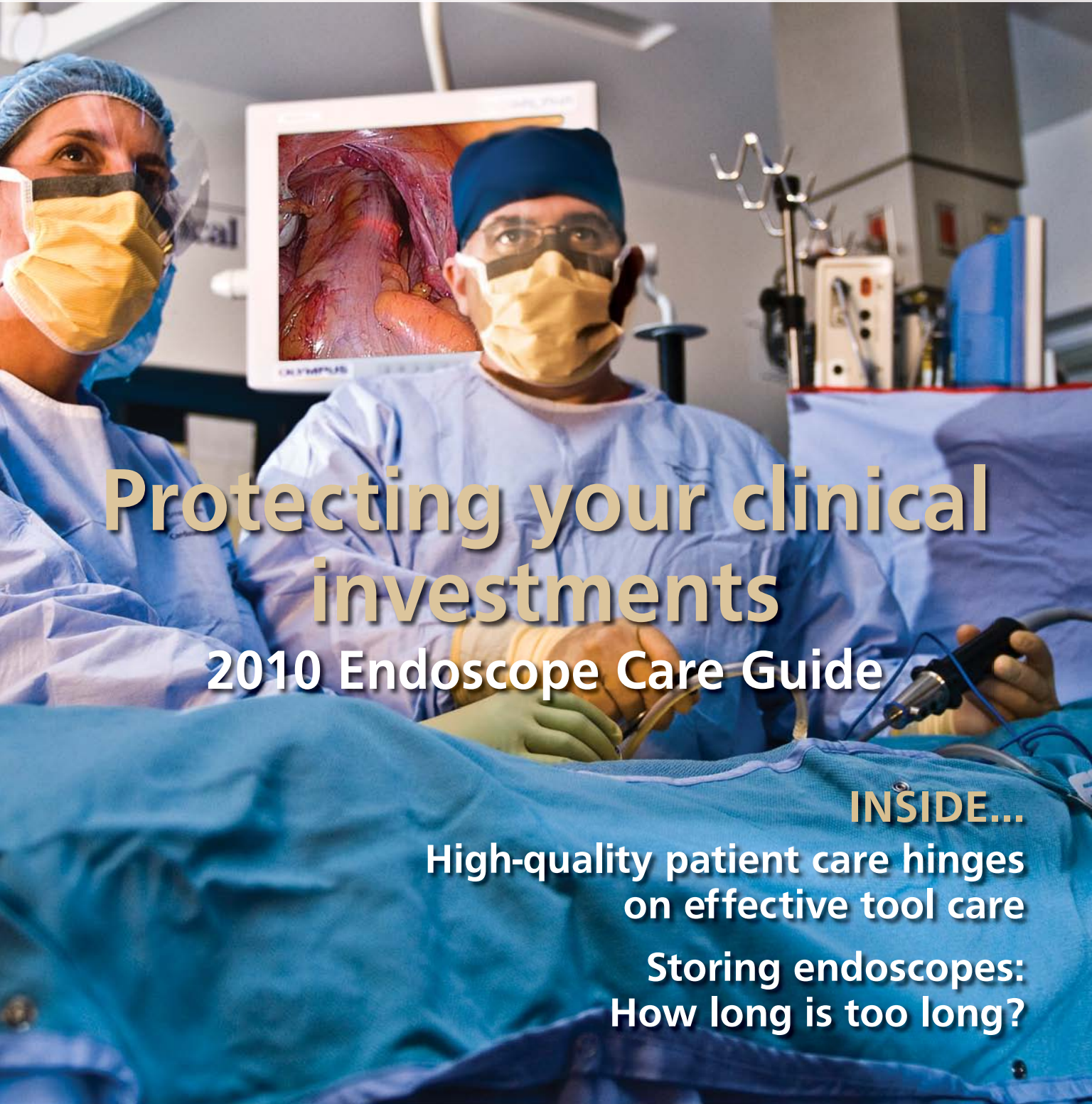
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2010 Endoscope Care Guide

INSIDE...

High-quality patient care hinges
on effective tool care

Storing endoscopes:
How long is too long?

High-quality patient care hinges on effective medical device care

Endoscopy success measured in repair and reprocessing

When the door to the surgical suite shuts, the nurses position themselves near the patient on the operating room table and the clinical tension starts to build there's little doubt that one of the key thoughts on the surgeon's mind as he or she enters the sterile field are the tools on the tray.

Those devices and instruments aren't generic products. They're tools he or she is comfortable using and can wield them with acute expertise. And they've hopefully been reprocessed or packaged completely and correctly. Anything short of that impacts the health of the patient lying on the table before him or her.

Certainly, tools do not make the heavily educated and trained professional who works with them. Instead they can affect the clinical outcome of the patient, which in turn reverberates throughout the healthcare delivery chain.

That's why *Healthcare Purchasing News* publishes its annual Endoscope Care Guide 2010, a November edition mainstay for the last six years. We created it as a reader service to provide hard-working clinicians and administrators with useful information on cleaning, disinfecting, sterilizing and repairing all types of flexible and rigid endoscopes thoroughly, efficiently and cost-effectively.

HPN's exclusive guide also highlights the obvious and overlooked dangers from improper cleaning, repair and storage, and identifies best practices for device longevity and reliability. After all, proper tool care can produce high-quality patient care.

We recruited experts and professionals from some of the leading companies that manufacture endoscopic products and offer endoscopic care services to share their expertise on making sure these costly surgical tools are ready for action all year long.

What you read here and learn may help you down the road, whether an administrator, clinician or patient.

Storing endoscopes: How long is too long?

by Bradley J. Catalone, Ph.D., and Mary Ann Drosnock, MS

For many flexible endoscopes, length of storage is not an issue because they are routinely used and rarely remain idle for more than a day or two.

However, other endoscopes, such as back-up equipment or specialty scopes, might be used less frequently. The question is, how long can these idle scopes be stored before additional reprocessing is required prior to use? In other words, does the duration of the storage period pose an infection risk to patients? In order to answer that question, you need to consider society guidelines for endoscope storage requirements, as well as the available data from scientific studies.

Professional society guidelines

Before we can evaluate how long a scope can remain in storage and safely stay patient-ready, we have to start with the premise that the scopes are reprocessed properly and stored properly, according to professional guidelines and standards. Because proper reprocessing is clearly defined according to the professional guidelines and standards, as well as instructions from the manufacturer, an in-depth explanation

of endoscope reprocessing will not be addressed here.

Appropriate storage environment

A proper storage environment is one that both protects the endoscope from damage and minimizes environmental contamination. Multi-society guidelines call for storing endoscopes in a manner that will protect the endoscope from contamination. During storage, endoscopes should hang in a vertical position to facilitate drying, with caps, valves and other detachable components removed following the manufacturer's instructions.

In addition, the Society of Gastroenterology Nurses and Associates (SGNA) not only recommends that stored endoscopes hang vertically, but also that the distal tip hangs freely in a well-ventilated, dust-free area. Good ventilation encourages continued air drying of the surfaces and prevents undue moisture build-up, thus discouraging any microbial proliferation. Also, padding the lower portion of the storage area with non-porous materials will help prevent

damage by protecting the scope and its distal tip from physical impact. Storage surfaces should be of a material that can be cleaned and disinfected easily and accessories should not only be removed, but also stored separately from endoscopes to avoid accidental punctures or cuts.

Safe storage duration

So assuming all of the criteria are met for proper reprocessing and storage, how long can you store an endoscope before reprocessing is required prior to next use? Currently, only one professional society, the Association of periOperative Registered Nurses (AORN), has issued a recommended practice relative to endoscope storage duration. In their 2009 Perioperative Standards and Recommended Practices, AORN recommends that flexible endoscopes be reprocessed before use if unused for more than five days. AORN's prior recommendation was to reprocess endoscopes immediately prior to next use, so this new 2009 recommendation represents AORN's acceptance that endoscopes can be stored and maintained in a patient-ready state for a limited time period.

Available scientific data

To come up with their recommendation restricting endoscope storage to five days, AORN cited the following four studies. A brief summary of each study is presented below.

Study 1: Bacteriologic testing of endoscopes after high-level disinfection. (2004)

This study was performed in two phases, both of which involved the sampling of clinically used gastroscopes, duodenoscopes and colonoscopes. In this study, external surfaces (i.e., valve cylinders and the distal end) and the instrument/suction channel of the endoscopes were sampled. For Phase I, 15 endoscopes of each type were sampled each day for five consecutive days. Four of the 135 samples were positive for microorganisms. Three of the four samples were from surface or channel openings and all were identified as skin bacteria. For all positive samples, the sample taken the day prior to and after the positive sample was negative for microbial growth. The second study involved sampling 10 endoscopes (channel sample only) after five days of storage with no positive recovery.

Findings: No recovery of clinically relevant microorganisms after five days of storage. (Positive results were attributed to contamination during sampling or endoscope handling.)

Observations: This study was performed in Europe where the efficacy requirements for high-level disinfectants are different than in the United States. In addition, a terminal alcohol flush of the endoscope channels was not performed following the final rinse. This is a step recommended by both professional endoscopy societies and endoscope manufacturers as a primary means to reduce residual moisture and, therefore, the risk of microbial proliferation in the endoscope channels. All positive samples were identified as skin bacteria, which is indicative of sample contamination. This is further supported by the fact that no microorganisms were recovered the day prior to or after the positive sample. This study only tested a storage period from one to five days.

Study 2: Establishing the shelf life of flexible colonoscopes. (2002)

This was a simulated-use study in which flexible colonoscopes were inoculated with a bacterial broth suspension and then manually cleaned followed by terminal reprocessing in the STERIS System 1 processor. The instrument/suction and air/water



channels of reprocessed endoscopes were then sampled after one and seven days of storage. A total of five colonoscopes were cultured following storage. No microorganisms were recovered after one day of storage. One positive sample was collected from the instrument/suction channel after one week of storage, and it was attributed to sample contamination.

Findings: No recovery of clinically relevant microorganisms after seven days of storage. (Positive results were attributed to contamination during sampling or endoscope handling.)

Observations: This was a simulated-use study, in which only five endoscopes were sampled twice, once on the first day of storage and again on the seventh day. The channels were flushed with 100 percent isopropyl alcohol (IPA) following the final rinse in the STERIS System 1. In the United States, 70 percent IPA is recommended as it evaporates at a slower rate than 100 percent IPA, thereby increasing the contact time of the alcohol with the surface. No positive control was performed to confirm that the inoculation methodology was adequate to simulate recovery of clinical microorganisms following patient use. The only positive sample was identified as skin bacteria, which is indicative of sample contamination.

Study 3: Reprocessing flexible gastrointestinal endoscopes after a period of disuse: Is it necessary? (2007)

This study involved clinically used endoscopes and was performed in three separate phases. In the first two phases, the endoscopes (colonoscopes and duodenoscopes) were sampled immediately after disinfection and then daily thereafter for a two-week storage period. In the third phase, the endoscopes were sampled after disinfection and after seven days of storage. For each phase, the instrument/suction channel of the endoscope was sampled and cultured for residual microorganisms. In Phase I, six of 70 samples were positive for skin organisms during the first five days of storage, with no recovery following six to 14 days of storage. No microorganisms were recovered from Phase II, which was a repeat of the Phase I study. In Phase III, there was only one positive culture, which was also identified as a skin organism.

Findings: No recovery of clinically relevant microorganisms after 14 days of storage. (Positive results were attributed to contamination during sampling or endoscope handling.)

Observations: In all three phases of this study, all positive samples were identified as skin bacteria, which again is indicative of sample contamination.

Study 4: Challenging endoscopy reprocessing guidelines: a prospective study investigating the safe shelf life of flexible endoscopes in a tertiary gastroenterology unit. (2007)

This study evaluated 23 clinically used endoscopes and was the most comprehensive study cited. Endoscopes were sampled after storage of five hours up to one week. For each endoscope sampled, different sample sites (all endoscope channels) were pooled into one common sample and tested for residual microorganisms.

Findings: With the exception of one sample, all positive samples in this study were indicative of sample contamination (based on microorganism identification). Only one in 194 samples was positive for a potentially pathogenic microorganism (i.e., yeast). In addition, four scopes were sampled after more than one week of storage (range 10-445 days) and were negative for microbial contamination.

Observations: The overall contamination rate of 15.5 percent suggests that the scopes in this study were not adequately reprocessed or contamination was being introduced during the sampling process.

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This is further supported by the 12.9 percent contamination rate just 24 hours after reprocessing. This is not consistent with the other studies reviewed here. Also, the samples from each scope were pooled, preventing any investigation to determine the source of the contaminant. Furthermore, the scopes were not sampled immediately after reprocessing to establish a baseline of effective reprocessing, so it is difficult to draw any significant findings from this study.

Patient-ready state

After reviewing the four cited articles, there was no valid scientific evidence presented that suggests storage of endoscopes for up to 14 days presents any risk to patient safety. In fact, there was no storage duration identified in these studies (even beyond 14 days) indicating that endoscopes should be reprocessed prior to next use. In each of the first three studies, the only organisms recovered were identified as skin organisms. These positive recoveries were most likely the result of sample contamination. The fourth study did not appear to have the proper controls, the data suggests significant levels of sample contamination, and the efficacy of the reprocessing procedure used is in question. As a

result, this study should be excluded as a reference for establishing any recommendation. Collectively, these studies support endoscope storage for at least 14 days. At this time, there is no published data that indicates that endoscopes cannot be maintained in a patient-ready state for more than 14 days.

What is also evident from these studies is that endoscopes are complex devices requiring a certain level of experience to effectively sample without introducing a contaminant. Facilities should carefully consider any program that includes routine microbiological sampling of endoscopes and should ensure that staff are properly trained to perform this testing.

In our opinion, the three most important factors in maintaining an endoscope in a patient-ready state are the effectiveness of the facility's reprocessing protocols (do they reprocess endoscopes according to manufacturer's instructions and professional guideline/standards), how well the endoscope is dried (do they perform an alcohol flush and air purge prior to storage), and the endoscope storage conditions (no caps or valves attached, hung vertically in a clean, well-ventilated cabinet, ambient temperature and relative humidity between 30 percent and 60 percent).

Each facility needs to evaluate their policy on the acceptable duration of endoscope storage based on their reprocessing efficacy and storage protocols. Understanding the current society guidelines and available scientific data will help your facility establish an appropriate policy on endoscope storage.

Bradley J. Catalone, Ph.D., is director of clinical affairs, and Mary Ann Drosnock, MS, is infection control scientist for Olympus America Inc., Medical Systems Group.

References:

- 1 Multi-society Guideline for Reprocessing of Flexible Gastrointestinal Endoscopes (2003), items 20 and 21.
- 2 SGNA Standards of Infection Control in Reprocessing of Flexible Gastrointestinal (2008), section K-Storage, items 1, 1a and 1b.
- 3 AORN Recommended Practices for Cleaning and Processing Flexible Endoscopes and Endoscope Accessories (2009), Recommendation IX.b.
- 4 Rejchrt S, Cermak P, Pavlatova L, McKova E, Bures J. Bacteriologic testing of endoscopes after high-level disinfection. *Gastrointest Endosc* 2004; 60(1): 76.
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