

The Q-Net™ Monthly

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What's News

Happy New Year. The FDA recently warned users about the **STERIS System 1**. Stating that this device is adulterated, misbranded, and poses the potential for injury both to patients and healthcare staff, the FDA expects medical facilities to stop using the System 1 within 3 to 6 months. For more details, visit the website: www.MyEndoSite.com

Editor-in-Chief

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What is 'Q-Net'?

Q-Net is a technology assessment, infection control-based network of questions, answers, and perspectives. Its newsletter is *The Q-Net™ Monthly*.

The main goal of **Q-Net** is to encourage the infection control, endoscopy, and operating room communities to improve patient care by not only asking good questions but also by demanding well referenced, evidence-based answers.

Q-Net addresses the needs of both the healthcare provider, whose goal is to provide the best care possible, and the patient, who deserves affordable quality health care.

Endoscope Storage Revisited

QUESTION: "I am reading conflicting reports about a stored flexible endoscope's shelf life. For how long can a GI endoscope be safely stored without requiring re-processing before its reuse?"



INTRODUCTION—ENDOSCOPE DRY-ING: A flexible endoscope may feature several complex internal channels, including, for example, a working channel. Some types and models of endoscopes may also feature a narrow elevator-wire channel. Like a long drinking straw, these channels can retain or trap rinse water, which, if contaminated with microorganisms, can pose an increased risk of healthcare-associated infections during flexible endoscopy.¹⁻⁷

As important as cleaning and high-level disinfection, proper drying and storage of the endoscope are crucial to remove remaining rinse water and prevent the growth of opportunistic microorganisms within its internal channels.¹⁻⁶ Indeed, improperly dried and stored flexible endoscopes—such as "ERCP" endoscopes and bronchoscopes—have been directly linked to patient morbidity and mortality.¹⁻⁷

How is drying achieved? Drying is typically achieved by manually flushing each of the endoscope's internal channels with

70% (isopropyl) alcohol, followed by forced or compressed air.^{1,2} (Refer to the endoscope manufacturer's instructions for the volume of 70% alcohol required to flush each channel.) Similarly, the endoscope's exterior may be dried by wiping its surfaces with a clean or sterile gauze pad moistened with 70% alcohol.

By reducing the surface tension of water and aiding its evaporation, 70% alcohol facilitates the drying of the endoscope's internal channels (and external surfaces).¹ Methods to verify whether the endoscope was adequately dried may include visual examination of the endoscope's distal tip for water droplets, or placing a clean piece of tissue paper underneath the hanging endoscope's distal tip during storage and observing the paper for water spotting.

When is drying necessary? Endoscope-reprocessing guidelines recommend drying the endoscope at the end of the
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Published Studies	Type of Endoscopes	# of Days
Osborne et al. (2007) ⁵	lower and upper GI endoscopes, including ERCP endoscopes and ultrasound endoscopes	1 day [†]
Pineau et al. (2008) ²	colonoscopes, duodenoscopes and enteroscopes	2-3 days ^{**}
Rejchrt et al. (2004) ¹⁰	lower and upper GI endoscopes, including ERCP endoscopes*	5 days
Riley et al. (2002) ⁴	colonoscopes	7 days
Vergis et al. (2007) ⁶	colonoscopes and ERCP endoscopes*	7-14 days

Table 1. The number of days that studies suggest a specific type of endoscope can be safely stored.

[†] This study suggests that a 5-day shelf life may be safe.

* The elevator-wire channel was not studied.

** Provided the endoscope is stored in a specific type of environmentally-controlled drying cabinet.

day, before its storage.^{1,3,7,8} Adhering to the long-standing infection-control principle that water or moisture on an instrument's surfaces (or wrapping) poses an increased risk of contamination, some guidelines, however, also prudently recommend drying the endoscope *between patient procedures*, to ensure the clinical use of a dry instrument.^{1,3,7,9} As Muscarella has published,⁹ few medical practices violate infection-control principles more noticeably and pose more of a risk of opportunistic infections than, for example, the introduction of a bronchoscope—just reprocessed and still wet with rinse water—into a patient's lungs. (Some guidelines and product labeling have confusingly endorsed this practice.^{7,8} Please refer to this newsletter's January-February, 2004, issue.)

ENDOSCOPE STORAGE: In addition to *drying*, endoscope-reprocessing guidelines emphasize the importance of proper *storage*, recommending, for example, that the reprocessed and dried endoscope be vertically hung in a dry, clean, and well-ventilated area or storage cabinet.¹ These guidelines further recommend that the endoscope's valves (e.g., suction, air/water) and other detachable components be removed, to prevent the endoscope's internal channels from retaining water, which could become contaminated with microorganisms and pose an increased risk of healthcare-acquired infection.¹

Storage time: Displayed in Table 1, the number of days that studies suggest a gastrointestinal (GI) endoscope can be safely stored is not well-defined. Concerned about the poten-

tial for microbial contamination and growth within the endoscope's internal channels during storage, some guidelines recommend that every endoscope be reprocessed (again) just prior to reuse (*see*: Table 2).^{3,5,7,8} Others, however, disavow this practice, noting that published data, although limited (*see*: Table 1), suggest instead that the endoscope can be safely stored for 1 day,⁵ 2-3,² 5,^{5,10,11} 7,^{4,6} or 14 days.⁶

Indeed, some guidelines place no specific limit on the number of days that an endoscope can be safely stored (*see*: Table 2).^{1,3} Concluding that insufficient data are available to require that a properly stored endoscope be reprocessed (again) prior to its reuse (or after a certain number of days), these latter guidelines—having adopted an *event*-related (as opposed to a *time*-related) paradigm—assert that the endoscope can be stored indefinitely—*provided*, however, that the endoscope was reprocessed and dried prior to storage in strict accordance with the instructions of published infection-control guidelines.^{1,4,10}

Some guidelines and studies suggest that gastrointestinal (GI) endoscopes can be safely stored for 1,⁵ 2-3,^{2,29} 5,^{5,10,11} 7,^{4,6} or 14 days.⁶

Published studies: While published data are scant, Pineau et al. (2008)² suggest that colonoscopes stored for 2 to 3 days in a specific manufacturer's environmentally-controlled drying cabinet do not require reprocessing before reuse. Two other studies suggest that ERCP endoscopes⁶ and colonoscopes^{4,6} can be safely stored for 7 days,⁴ or as long as two weeks⁶ (*see*: Table 1). (Please refer to the *box article* on p. 24S₁.)

Similarly, Rejchrt et al. (2004)¹⁰ reported that lower and upper GI endoscopes, including ERCP endoscopes, can be safely stored for as many as 5 days, though, as with some other studies,⁶ the ERCP endoscope's elevator-wire channel—which when improperly reprocessed and dried has been directly linked to disease transmission⁷—was not studied. Osborne et al. (2007)⁵ reported that properly reprocessed, dried, and stored endoscopes may be safely stored overnight and possibly for 5 days or longer.⁵

RECOMMENDATIONS: Reports suggest that endoscope-drying and storage practices, like cleaning and high-level disinfection, may vary considerably from one facility to another.^{4,12} Moreover, first addressed in this newsletter in 1998¹³ and again in 2000,¹⁴ the data to support claims that a GI endoscope can be safely stored for a specific period of time (e.g., 3 hours; or 2-3, 5 or 7 days; *see*: Table 1) without requiring reprocessing before its reuse are limited, if not at variance.³ (Please refer to the *box article* on p. 24S₁.) More research is necessary to determine the “safe” shelf life of different types and models of flexible endoscopes, including not only colonoscopes but also ERCP endoscopes and bronchoscopes.

The following recommendations provide guidance to reduce the risk of disease transmission:

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1. As part of the reprocessing protocol, **dry the endoscope's internal channels and exterior using 70% alcohol** in accordance with published guidelines.^{1,15} Perform this step between patient procedures *and* before storage, no matter whether manually reprocessing the endoscope or using an automated endoscope reprocessor (AER); or whether using sterile, "sterile" filtered, bacteria-free, or tap water for rinsing.¹

2. After drying it, **store the endoscope** in accordance with published guidelines.^{1,15,16} For example, hang the endoscope vertically in a clean, dry, well-ventilated area or storage cabinet with the endoscope's valves, biopsy cap, and other detachable components removed, to facilitate drying.^{1,15}

3. **Establish a quality assurance program** that (*see*: the *box article* in the right-hand column of this page):

- (a) **ensures** that the endoscope removed from storage was properly reprocessed (and dried) *prior* to storage (*see*: the *blog* article on p. 24S₂);¹⁵
- (b) **establishes** that the environment or cabinet in which the endoscope was stored is monitored and controlled, to promote drying and prevent the growth of microorganisms within the endoscope's internal channels; and
- (c) **documents** the number of days each flexible endoscope, identified by its model and serial number, has been in storage (this practice would not be necessary if the medical facility reprocesses every endoscope before its reuse).

4. Medical facilities with a quality assurance program in place (*see*: *recommendation #3*, above) may **consider storing upper and lower GI endoscopes** (with the exception of ERCP endoscopes; *see*: *recommendation #7*, below) **for as many as 7 days**, without having to reprocess the endoscope before its reuse. (Whether this recommendation—which is based on limited data and may be revised as additional data are published—can be soundly applied to other types of flexible endoscopes, such as cystoscopes, is unclear.)

(Alternatively, in compliance with one published guideline,¹¹ medical facilities may consider reprocessing before its reuse any flexible endoscope stored for more than **5 days**.)

5. **Examine each endoscope removed from storage prior to its use.** Remove from service any endoscope identified to be damaged or otherwise unsafe for clinical use.

6. **Reprocess a stored endoscope before its reuse if:**

- (a) the facility does not have in place a quality assurance program (*see*: *recommendation #3*, above) that ensures the endoscope was reprocessed, dried, and stored in accordance with published guidelines;^{1,15-19}
- (b) the facility's quality assurance program is imperfect and

the endoscope is removed from storage and identified by staff to be contaminated or to have been improperly reprocessed, dried, or stored—for example:

- (i) the endoscope is observed to be wet;
- (ii) the endoscope's distal tip is touching the ground;
- (iii) the endoscope's valves had not been removed;
- (iv) the endoscope had been stored in an AER, automated "sterilizing" processor,⁴ or pillow or carrying case;¹⁶

(Continued on page 24S₂)

Box A. **Factors affecting an endoscope's shelf life.**

Not every medical facility has in place an adequate quality assurance program for monitoring and controlling the environment in which flexible endoscopes may be safely stored, or for documenting the number of days each specific type and model of endoscope has been in storage. Without such a program, however, every flexible endoscope (with internal channels) would arguably require reprocessing before its reuse, because whether (and the number of days) the endoscope had been safely stored would not ordinarily be known.

Further, most studies assessing the potential for microbial colonization during storage focus primarily on the working and air/water channels of GI endoscopes. While published data suggesting a "safe" shelf life for gastroscopes and colonoscopes appear sound,^{2,4-6,10} the extent to which these data can be applied directly to, for example, the complex elevator-wire channel of an ERCP endoscope,^{6,10} or the working channel of a bronchoscope or other type of flexible endoscope, is unclear.

Warranting consideration and circumspection, the length of time that a flexible endoscope might be safely stored without requiring reprocessing before reuse depends, not only on the specific storage conditions (e.g., cleanliness, the relative humidity) and how effectively the endoscope was dried prior to storage—factors that may vary from one facility to the next¹²—but also on the flexible endoscope's specific type (i.e., Pentax, Olympus, Fujinon) and model (e.g., ERCP endoscope, colonoscope).²

Indeed, the design of different types and models of flexible endoscopes—whose internal channels can be complex, hinder drying, and provide the ideal environment for the growth of microorganisms—may vary significantly.² Similarly, the susceptibility to infections of the different viscera into which flexible endoscopes are introduced (e.g., the colon, lungs), too, can vary markedly.

As a result of these (and other) factors, *the extent to which any guideline or study defining an endoscope's "safe" shelf life can be universally adopted is limited.* That the specific number of days that a GI endoscope might be safely stored cannot necessarily be generalized and applied to all types and models of flexible endoscopes is an important consideration with salient infection-control and healthcare-management implications. ● LFM

(v) the endoscope had been used during off hours and was not reprocessed by trained staff members prior to being placed back into storage; or

(c) the facility's rinse water contains significant numbers of opportunistic microorganisms.¹⁷

7. Consider reprocessing ERCP endoscopes and bronchoscope (and, possibly, enteroscopes) before their reuse, whether or not an adequate quality assurance program is in place.²⁹⁻³¹ (Published data in support of this recommendation are admittedly limited, though not lacking.) ● LFM

Q-Net Blog: The STERIS System 1

That it would be removed from the market because of regulatory breaches was arguably inevitable. As many as 15 years ago, this newsletter's editor expressed to a non-profit healthcare institute (his employer at the time) his concerns that the STERIS System 1 and its labeling claims were faulty and posed an increased risk of patient injury (see: the September-October, 2008, issue of this newsletter entitled, "Let sleeping dogs lie?").²⁰ These concerns were published on the front page of "The Wall Street Journal" and in "Investors Business Daily."^{20,21}

With some insight into the rationale for the regulatory actions that were to take place just weeks later, both the July-August-September, 2009, and October-November, 2009, issues of this newsletter question the safety and labeling of the STERIS System 1. Concluding earlier this month (December, 2009) that it could cause serious injuries (such as infections) to patients,^{22,23} the FDA has instructed healthcare facilities to stop using the System 1 within 3 to 6 months. Every model and serial number, dating back more than 20 years, are subject to this action.

The FDA's rebuke of the STERIS System 1 is not surprising to some who have studied this device's marketing, labeling and use. Indeed, the System 1's operation is not consistent with aseptic technique, its "sterilization" claim and "guarantee" are dubious, and its contraindication²⁴ of endoscope drying (using 70% alcohol) a health risk. To be sure, the facts indisputably support the FDA's actions. As detailed in a letter it wrote to Steris on April 23, 2001, the FDA, having associated the device with patient injuries, questioned the System 1's ability to "sterilize" and to produce "sterile" rinse water.²⁵⁻²⁷

That the healthcare community reportedly was unprepared for (and devastated²³ by) the FDA's de-facto recall²⁸ of the System 1 is notable—because through the years there had been data, FDA-warning letters, and articles presented in the medical literature and the press^{20,21} raising valid concerns about the System 1's safety, "guarantees," and labeling. The System 1 teaches us many lessons, an important one of which is to ensure that the marketing claims of medical devices are scientifically scrutinized and supported by sound data. ● LFM

Organization	Endoscope Type	Shelf-life
AORN (2009) ¹¹	Flexible endoscopes	> 5 days
ASGE ¹⁵	GI endoscopes	Indefinite
BSG ¹⁹	GI endoscopes	3 hours [†]
BTS ¹⁷	Bronchoscopes	None
CHA ^{6,10}	Flexible endoscopes	12 hours
GESA/GENCA ^{29,30}	ERCP endoscopes	None
SGNA ¹	GI endoscopes	Indefinite
WGO ¹⁸	GI endoscopes	Indefinite

Table 2. The organization and the number of hours or days that it recommends a flexible endoscope can be safely stored (provided the endoscope was properly cleaned, disinfected, and dried prior to storage).

[†] The BSG suggests that the use of validated drying cabinets may provide a "safe" shelf life of 3 to 7 days.

LEGEND. AORN: Association of periOperative Registered Nurses; ASGE: American Society for Gastrointestinal Endoscopy; SGNA: Society of Gastroenterology Nurses and Associates; BSG: British Society of Gastroenterology; WGO: World Gastroenterology Organization; BTS: British Thoracic Society; CHA: Czech Hygiene Authorities; GESA/GENCA: Gastroenterological Society of Australia and Gastroenterological Nurses College of Australia.

The REFERENCES to this article are available on-line at:
 ➔ www.myendosite.com/htmlsite/2009/refs1209.pdf

Thank you for your interest in this newsletter. I have addressed each issue and topic to the best of my ability. Respectfully, **Lawrence F. Muscarella, Ph.D.**
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