Letters to the Editor

STERIS SYSTEM 1 in Germany

To the Editor:

As my American infection control friends know, we Germans are sometimes stricter than the Pope in Rome. Regarding the STERIS SYSTEM 1; however, I think we are on the right track. The system disinfects endoscopes, that is, makes them microbiologically clean enough so that they do not transmit infection anymore, but it does not sterilize, which would mean killing all microorganisms including spores, even if they were present in very high numbers.

The STERIS Corporation tried to market the system in Germany with the help of an established endoscope manufacturer, for whom we tested the system in 1990 (unpublished data). We contaminated colonoscopes and gastroscopes with 10^8 colony forming units (cfu)/mL of Staphylococcus *aureus*, Enterococcus *faecium*, Mycobacterium *terrae*, Candida *albicans*, and *Pseudomonas aeruginosa* in human blood. Only when the endoscopes were cleaned very carefully, which by itself reduced the colony count by 10^3 to 10^4 cfu/mL, was the STERIS SYSTEM 1 able to "sterilize." If high bacterial counts remained in the channels and on the valves, the STERIS SYSTEM 1 was able neither to disinfect (reduction of colony count by at least 100,000-fold) nor to sterilize. We all know that careful cleaning of endoscopes is time-consuming and, therefore, often not performed thoroughly in hospital routine.

Therefore, we strongly recommended to our clients that they not market the STERIS SYSTEM 1 in Germany for the sterilization of endoscopes.

Franz Daschner, MD
Freiburg, Germany

The author replies.

Prof. Dr. ED. Daschner has written to you as a result of my article published in the June 1993 issue of *Infection Control and Hospital Epidemiology* entitled "Use of Biological Indicators Designed for Steam or Ethylene Oxide to Monitor a Liquid Chemical Sterilization Process." Although I do not see anything in his letter related to my manuscript, I do appreciate his letter and would like to respond.

Dr. Daschner asks, "Does STERIS SYSTEM 1 sterilize?"

Yes, it does, as evidenced by its efficacy in meeting the stringent requirements of the Food Drug Administration (FDA) for sterile processing systems and the Environmental Protection Agency (EPA) for liquid chemical sterilants. The efficacy also has been demonstrated in numerous independent studies and in millions of uses in thousands of major medical centers, hospitals, surgical centers, and other healthcare facilities throughout the United States and in many foreign countries.

Does STERIS SYSTEM 1 clean grossly contaminated flexible endoscopes? According to Dr. Daschner's letter, it certainly appears that STERIS SYSTEM 1 is quite effective in removing significant bioburden under extremely adverse conditions. However, STERIS specifically makes no cleaning claims. Rather, we agree with the positions, guidelines, and recommendations of the Centers for Disease Control and Prevention, AORN, SGNA, ASGE, Association for Professionals in Infection Control and Epidemiology, and other organizations that devices must be thoroughly cleaned prior to sterile processing. This point is emphasized throughout the 2-day STERIS SYSTEM 1 Operator Training Program that has been attended by more than 2,200 healthcare professionals. We at STERIS are unaware of any system for low temperature sterilization or disinfection of surgical and diagnostic devices that has been cleared for marketing in the United States by the FDA that does not require cleaning of the devices prior to processing.

I observed the method of contamination of flexible endoscopes that Dr. Daschner used when he "tested the system." Freshly drawn whole human blood was mixed with a high concentration suspension of microorganisms. This fresh whole blood/microorganisms mixture then was injected with a syringe through the all-channel irrigator into a flexible endoscope until the mixture dripped from the distal end of the scope. All internal channels of the scope, including those channels normally not exposed to organic soil, were filled with the blood-based mixture. The injected mixture then was allowed to coagulate and dry prior to placing the endoscope in STERIS SYSTEM 1 for processing. I informed Dr. Daschner that the test conditions he was creating were inconsistent with the claims and instructions for use of STERIS SYSTEM 1.

Dr. Daschner tested STERIS SYSTEM 1 contrary to its claims and instructions for use. As we in the sterilization field agree, every process can be defeated if challenged in ways inconsistent with the intended use of the process or system.

Given the severity of the soil challenge used by Dr. Daschner, his letter is a positive statement on the efficacy of STERIS SYSTEM 1. I know of no other low-temperature sterile processing system, including ethylene oxide or vaporized hydrogen peroxide, that can disinfect grossly contaminated flexible endoscopes in a single cycle. Dr. Daschner also acknowledges the STERIS SYSTEM 1 was able to sterilize flexible endoscopes that were cleaned prior to

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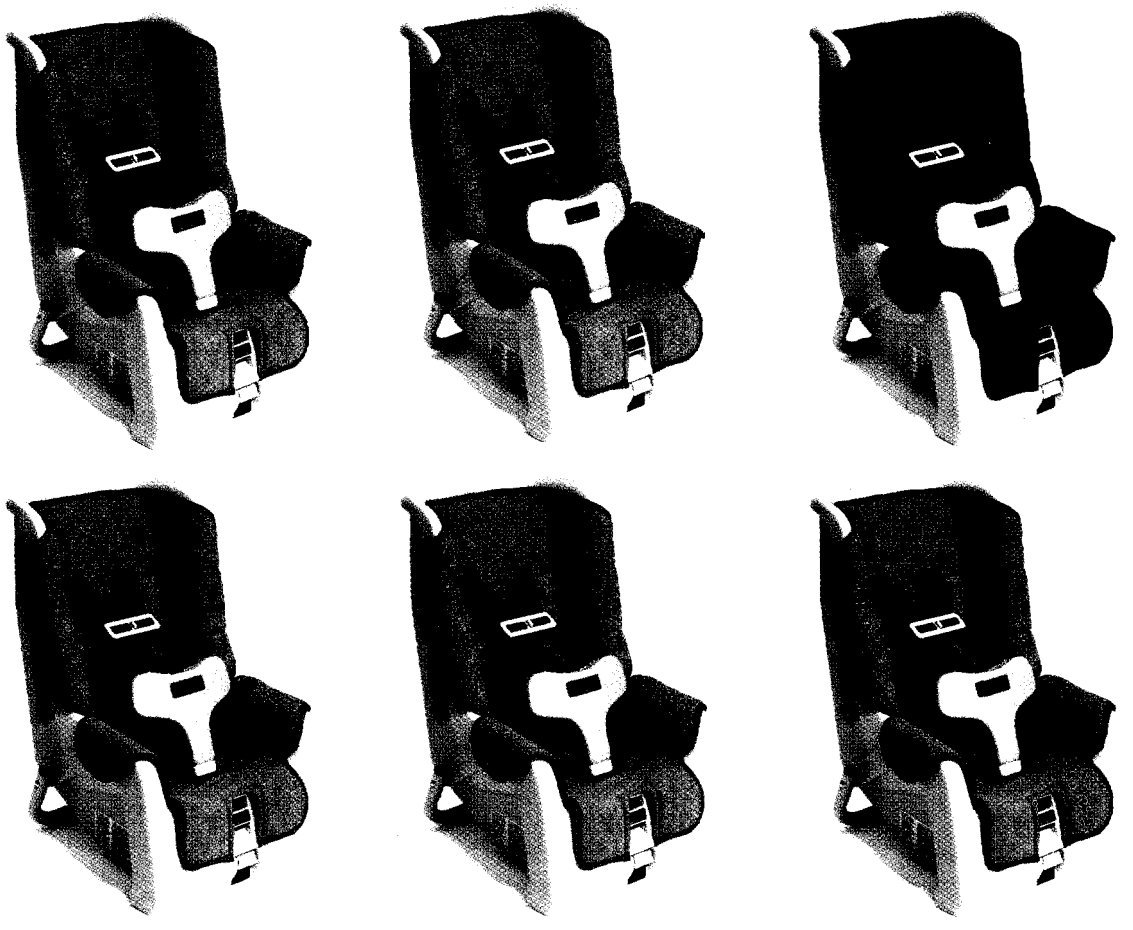

If the blue one protected 4 times better, would you use it?

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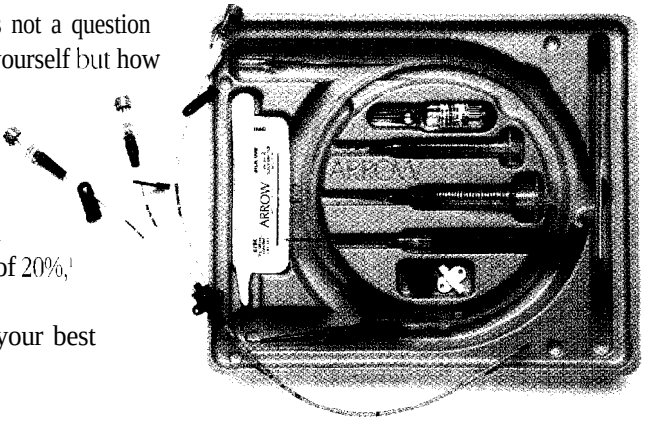

CVC catheters with the built-in protection of ARROWg+ard Blue"' are **up to 80%** less likely to develop bacteremia than unprotected catheters.' So you can save up to 80% of your CVC patients from the risk of a catheter-related bloodstream infection. And you can save your hospital from the expense of $7,000 per infection.

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Elliot, TSJ Intravascular-device related infections J Med Microbiol; 27:161-167; 1966 ARROWgard Blue™ is a joint development of Daltex Medical Services, Inc and Arrow International, Incusing technology developed by DrShantaModak and colleagues, in the Department of Surgery Columbia University U S Patent Numbers 4 612,337, 4,563.485 4,581 028, 5.019 096. other U S and foreign patents pending ² Maki, DG. Wheeler, SJ; Stolz, SM: Study of a novel ant septic coated central venous catheter. Presented at the Society of Critical Care Medicine Annual Symposium; Washington, D C May 1991.

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TABLE 2
POPULATION OF SPORES ON BIS BEFORE AND AFTER EXPOSURE TO THE LIQUID CHEMICAL STERILIZATION CYCLE

BI Tested	Test No.	CFU Strip Control	CFU Strip Exposed	Significance (Control vs. Exposed)
NAmSA: *B stearothermophilus*	1	2.3 x 10"	8.8 x 10"	
	2	3.1 x 10"	3.8 x 10^4	
	3	2.0 x 10^5	1.5 x 10^5	
	4	1.1 x 10"	9.0 x 10^4	
	5	9.0 x 10"	1.2×10^5	
	6	8.0 x 10"		
	Mean	1.7 x 10^5	9.7 x 10"	E-0.05. $t = 1.63$, $df = 9$
NAmSA: *B subtilis*	1	4.0 x 10"	1.5 x 10"	
	2	2.0 x 10"	1.7 x 10"	
	3	2.2 x 10^6	9.0 x 10^5	
	4	1.0 x 10"	9.0 x 10^5	
	5	9.0 x 10"	1.2 x 10"	
	6	2.0 x 10"	1.3 x 10"	
	Mean	1.2 x 10^6	1.3 x 10^6	$P>0.05$, t=-0.06, $df = 10$

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processing. This is precisely what STERIS SYSTEM 1 is designed to do.

Dr. Daschner's studies also sup port one of my beliefs, that the peracetic acid-based STERIS 20 liquid sterilant in a directed flow circulating system can provide a margin of safety in removing the small amounts of organic debris that may remain after cleaning of devices in the clinical setting. I am unaware of any gaseous process with the ability to remove even small amounts of residual bioburden.

My colleagues at STERIS and I thank Dr. Daschner for his remarks and would certainly be interested in working with him on further studies of the exceptional sterilization and cleaning capabilities of STERIS SYSTEM 1. Perhaps the current claims for the process are understated.

Raymond **C. Kralovic, PhD**
STERIS Corporation
Mentor, Ohio

Corrections

During production, a typographical error was introduced in the June 1993 article "Use of Biological Indicators Designed for Steam or Ethylene Oxide to Monitor a Liquid Chemical Sterilization Process" (Kralovic RC. 1993;14:313-319). In Table 2, page 316, the value for *B subtilis*, control #5, should be $9.0 \times$ lo", not 9.0×10^6. The corrected Table appears on this page. In addition, Dr. Kralovic has asked that an ambiguity be clarified. The last complete sentence on page 315 stated, "As shown in Table 3, only a small number of spores were recovered from *B stearothermophilus* or *B subtilis* spore strips (0.2 to 1.8%, respectively)." Dr. Kralovic believes his intent would be better understood were the sentence to read, "...only a small number of spores were removed..."

For the January 1994 review of *Epi-TUTOR* (1994;15:56-57), the reviewer worked with a prerelease version of the software. Dr. Birnbaum advises us that the released version 1.0 is available in two forms, a demo version ($45) similar to that reviewed and a fully functional version ($175). The latter provides 1,000 questions, prints test forms, and provides nurses with an opportunity to obtain CEU credits. Both versions require 1.5 to 2 megabytes of disk memory and at least 480K of free RAM. Single-user and educational site-licensed versions are available. Further information may be obtained from the U.S. distributor at (800) 984-9300. Note also that the study guides mentioned in the review are available from APIC, not CBIC. For information about the CBIC examination, contact the CBIC Executive Office, P.O. Box 14661, Lenexa, KS 66285-4661. To order APIC study guides, contact APIC, 1016 16th St., 6th Floor, Washington, DC 20036; telephone (202) 2962742.

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