

A NEW RISK FOR HIGH-TECH SURGERY?

Tough-To-Clean Endoscopes May Pose Hazard Of Infection

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If you live to be 55 or so, chances are you'll have a close encounter with a long, black snake-like creature called an endoscope.

That's usually all to the good. From removing gallstones and polyps to screening for cancer, endoscopes have revolutionized surgery the past 15 years.

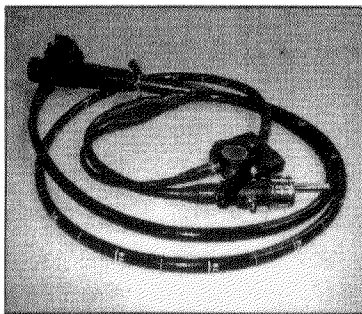
In many cases where a doctor would have cut open a patient even 10 years ago, the same procedure can be done by using an endoscope.

More than 10 million patients are prodded with endoscopes each year. And by reducing problems from invasive surgery and helping doctors detect diseases at an early stage, endoscopes have saved perhaps millions of lives.

Endoscopes are long tubes made from plastic rubber and steel, using fiber optics to help perform surgery. However, the same flexible design that lets endoscopes help doctors snake around the body also make them hard to clean.

Because many endoscopes are heat-sensitive, they can't be treated with steam, the preferred method of sterilization.

But an American Society for Gastrointestinal Endoscopy task force found the risks of contaminated en-



DIRTY SCOPES: Surgical endoscopes save lives but are tough to sterilize.

doscopes to be tiny: only 28 reported cases of infection transmission out of an estimated 40 million gastrointestinal endoscopies performed from 1988 to 1993, a risk of 1 in 1.8 million.

And every one of those resulted from a breach of cleaning and disinfection guidelines.

Still, media outlets from Newsweek to Time Inc.'s Hippocrates, a magazine for doctors, have splattered readers with stories of dirty endoscopes and claims that the risks are underreported.

The source for nearly every one of these stories? David Lewis, a research microbiologist at the Environmental Protection Agency on assignment to the University of Georgia. (Lewis also attracted media attention, including that of *IBD*, for his role as a whistle-blower critical of

the science policies of EPA head Carol Browner.)

In the articles about endoscopes, Lewis has often plugged the Steris System 1, a product made by a company for which he consults. Steris is the only liquid-chemical process the Food and Drug Administration has cleared to market as a sterilizer.

While Lewis says he takes no money from Steris Corp., based in Mentor, Ohio, the company does donate money to a Georgia church that Lewis cofounded.

Now Lewis is lobbying to get the Centers for Disease Control to change its guidelines from recommending high-level disinfection to sterilization.

In practice, that would mean hospitals that used liquid chemicals to reprocess endoscopes could use only Steris machines and its germicide.

Although the guidelines aren't rules, they can be used in medical malpractice lawsuits, which Lewis thinks are justified against doctors who don't "sterilize" their instruments.

"I just find it astounding that in the day in which we live we're arguing over whether you ought to sterilize a device that's used in surgery," Lewis said.

But the FDA aside, many infection-control experts say there are few data to show that Steris does any better job than the liquid-chem-

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cal germicides. And some say Lewis' claim may even harm patients by sending confusing signals to hospital staff about endoscopes being "sterile."

A study in the American Journal of Infection Control in 1998 found that the Steris System 1 failed to kill 37 out of 40 bacterial spores.

A Steris official and microbiologist Michelle Alfa both said that the specially built scope used in the study was not the kind used in a normal hospital. Another study funded partially by Steris in Gastrointestinal Endoscopy found that its competitors were just as effective as Steris in killing bacteria.

And CDC microbiologist Lynne Selhuster told *IBD* there's no independent research to show that endoscopes can be sterilized.

"The FDA's review is simply a clearance based on manufacturer-supplied data," she said. "When you look at the scientific literature that's available to the rest of the world, you don't see data that does not have any kind of corporate interest involved which supports the statement."

It's possible the FDA may have data "we're not privy to," she added.

Similarly, Franz Daschner, an official of Germany's National Reference Center for Hospital Hygiene in Berlin, said the claim is "definitely false. Steris may disinfect, but it definitely doesn't sterilize and kill all organisms. In Germany, we do not recognize (liquid) solutions as sterilizers."

Sterilization is defined as the killing of all microbial life, regardless of resistance. High-level disinfection is the killing of almost all disease-causing bacteria. Steris Vice President Paul Malchesky says the product provides the same sterility assurance level as steam that all microbes will be killed.

But others say liquid germicides, unlike steam, don't sterilize completely. Liquid may not penetrate all areas. And the instrument can't be wrapped in packaging and stay sterile while on

the shelf.

Also, as then-CDC branch chief Walter Bond argued in a 1993 article in the journal *Infection Control and Hospital Epidemiology*, sterility can't be monitored in the usual way, with a biological indicator. The reason: There's no way to tell whether the process killed the spores or whether they simply were washed off.

Although the FDA cleared a biological indicator for Steris' process in 1996, Malchesky and the FDA say it was to validate that it worked, not that the medical device is sterile.

And even if the liquid germicide did sterilize the scope, it still has to be rinsed off to prevent allergic reactions.

An automated endoscope reprocessor, like any automatic washer, must be hooked up to a dispenser of tap water, which can contain bacteria. Steris' Malchesky says the Steris System 1 produces sterile water through a special filter.

But "filtering tap water using the micron filter (like Steris') is unlikely to ever yield sterile water," said Lawrence Muscarella, infection control chief of Custom Ultrasonics, a Steris competitor that makes washer disinfectors. Muscarella and Daschner say only heat makes water sterile.

Lewis concedes the instruments may not always be sterile after they're sterilized.

"I'm not saying that every patient has got to have a sterile endoscope, just one that has been subjected to a sterilization procedure that gives you the best chance of having killed the micro-organisms there," he said.

Lewis said the criticism of his way of sterilizing is "just all about money. It's not that sterilizing these devices is going to hurt anybody."

But Muscarella argues that a false assurance of sterilization may have dangers.

For instance, hospital staffs may not take the precautions they would with disinfectants. He says this may

have been the case with four reported bacterial outbreaks in New York because of bronchoscopes processed in the Steris System 1.

At the New York Hospital Medical Center of Queens, three patients became seriously ill and one apparently died after becoming infected in 1998 with *Pseudomonas aeruginosa* — a rare bacteria that can kill people with weakened immune systems. State and federal health officials concluded last year that the reprocessors were wrongly hooked up with the bronchoscopes.

In December the FDA sent Steris a warning letter, saying the company "did not conduct an adequate investigation and/or adequately determine the cause" of the New York outbreaks and other cases in which patients were infected with tuberculosis and staphylococcus.

Muscarella thinks if the New York hospitals had used a 70% alcohol rinse and forced-air drying, steps routinely taken in high-level disinfection to keep bacteria from growing, the outbreaks might not have happened.

Sorona Segal-Maurer, an official of New York Hospital, said she was "pretty sure" alcohol and drying were used. But state health official Rachel Stricof said she doesn't recall finding that this step was taken. Neither could provide *IBD* documentation.

Steris' Malchesky says alcohol rinsing would be "detrimental, because now you're contaminating that scope with alcohol, which could be contaminated in and of itself."

But the FDA and the CDC suggested in September that hospitals should consider alcohol and drying as a final step. And Tim Ulatowski, FDA's director of dental, infection control and general hospital devices, says this includes the Steris System 1.

When asked if the system would be cleared for sterilization today, Ulatowski said only, "once a product is cleared, it's cleared."

He added the FDA cannot change a claim "until there's a problem."