

FIGURE. A grooved director is used to immobilize the Port-a-Cath.

in two patients with cytomegalovirus retinitis. Each healthcare worker stuck himself in the hand he used to immobilize the Port-a-Cath system while removing the needle with the other hand.

After these two accidents, we began to advise healthcare workers who use Port-a-Cath systems to use a grooved director (Figure) to immobilize the Port-a-Cath. Since then, no new Port-a-Cath needlesticks have been reported in our center.

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Biological Indicators for a Liquid Chemical Sterilizer

To the Editor:

The editorial recently written by Bond[1] is an interesting personal commentary. The editorialist takes issue not only with the use of biological indicators for a liquid chemical sterilizer as presented by Kralovic,[2] but also takes issue with the only system that employs an EPA registered sterilant and which, as a system (Processor and Sterilant), has FDA market clearance as a sterile processing system-namely, the STERIS SYSTEM 1 Processor with STERIS 20 Sterilant. He questions the EPA and FDA review process for this system. Bond offers a challenge to manufacturers of chemical germicides and reprocessing systems to "join with the infection control community in influencing governmental agencies to act accordingly under their existing regulatory authorities."[1] Further, he calls for medical instrument manufacturers to redesign devices and provide data-based instructions on access and cleaning. All this is done without providing the readers, and in general the infection control community and the public, with a sense of understanding of the progress that has and is being made to provide the practitioner with higher standards of care. Instead, he places fear and doom and gloom in not only the use of biological monitoring, but also STERIS SYSTEM 1, the process for regulatory approval, and present instrument designs.

Let's consider his discussion of biological monitoring first. He notes that to use biological monitors, designed for use with steam or ethylene oxide sterilization, by removing them from their containers and exposing them directly to a fluid environment to monitor the efficacy of a liquid chemical sterilization cycle is not warranted by the data presented by Kralovic.[2] Bond never directly addresses whether Kralovic's data are inaccurate or unwarranted. Instead, to support his conclusion, Bond attempts to refute Kralovic's argument that biological indicators can be used to monitor liquid chemical sterilization processors by stating that they do not offer proof of sterility of each individual item; conversely, he admits that they are not intended for this purpose. The purpose of a biological monitor is to demonstrate whether sterilization conditions were met.[3,4] For a liquid chemical sterilization system, that implies that the designated time of the cycle and the required concentration and temperature of the sterilant are achieved.

Regarding the issue raised by Bond of the appropriateness of the spore test species, published and accepted requirements for biological monitors are that the spores selected have demonstrable resistance to the sterilizing agent and that they be more resistant than the bioburden found on medical devices.[5] Kralovic demonstrated the resistance of *Bacillus stearothermophilus* and *Bacillus subtilis*.[2] It was shown that *B stearothermophilus* was two to three times more resistant to the sterilant than *B subtilis*.

Bond notes that spores may remain on the strip, but that 400 were removed from the *B stearothermophilus* strip (the strip chosen for subsequent use in monitoring the process). This represents only 0.2% of the total number of spores on the strip. What remained was more than "some"[1] that he notes. Why the loss of some spores may "eliminate any notion that this technique is suitable for routine monitoring of cycles in healthcare settings"[1] is not understandable. STERIS SYSTEM 1 is a closed system. Spores on the strip and any that may be separated from the strip are contained in the fluid and inactivated by the sterilant. Testing of the sterilant at the end of a sterilization cycle and tests of the rinse waters taken from the processor show that they are sterile. This indicates that even if spores are separated from the strip they are killed. The studies of Kralovic[2] point out that only a

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minor percentage of spores may be separated from the strips even under conditions of vigorous fluid mixing. Kralovic discusses thoroughly why the small number of spores that may be removed will not affect significantly the ability of the biological indicators to determine if sterilization conditions were present. Bond offers no scientific argument as to why Kralovic's interpretation of the data is invalid. Nor does Bond offer data to support his opinion.

Regarding the concern of possible peracetic acid (PA) residuals that he raises: peracetic acid is very labile. Testing of the use dilution of STERIS 20, under operating conditions of SYSTEM 1, has shown that the half-life of peracetic acid is about 20 minutes.[6] In a standard STERIS SYSTEM 1 Processor cycle, four separate water rinses of 10 L each are made, reducing residual sterilant concentration within the fluid to a level below detection (0.5 ppm PA).[2] For culturing, the strips are placed in culture medium that further reduces their concentration. The ability of sterilant on the spore strips to inhibit spore growth was tested by culture of sterilant-treated *B stearothermophilus* strips with a known number of like spores in media vials. There was no difference in the outgrowth for the spores in the presence of residual sterilant introduced into the growth medium by the spore strip as compared to spores incubated in its absence.[2] There is no demonstrated need for a neutralizer in the growth medium.

For market clearance of the STERIS PROCESS, extensive testing of the sterilant and the process, including the evaluation of devices for sterility, has been carried out and submitted to the EPA and FDA Device testing continues as a routine within STERIS in coop eration with instrument manufacturers and users to assess the sterilization of new reprocessable medical instruments. STERIS has worked with more than 100 medical instrument manufacturers and numerous users through its Device Testing Program in carrying out such assessments. No other sterilization/disinfection system manufacturer or sterilant/disinfectant producer can make such a claim, nor has been so dedicated to the continual evaluation of its process for use with medical instruments as has STERIS.

Bond takes difference with a number of the test methodologies that STERIS carried out in support of its EPA and FDA data submission for market clearance. Because of the uniqueness of the STERIS SYSTEM, these agencies recognized in the review process that the general methods applicable for conventional sterilants/disinfectants and processes would not be applicable directly to the STERIS liquid chemical sterilization system. Where methodological modifications were made they were recommended and/or accepted by the agencies. For example, silk suture loops traditionally are used in the AOAC methods of evaluating the efficacy of a sterilant. Silk is a protein, and as such, may be susceptible to chemical degradation by the peracetic acid, the active sterilizing agent in STERIS 20. STERIS requested and received written approval to substitute dacron for silk after having demonstrated the spore loading equivalency and HCl resistivity with the two materials.

Bond's concerns over some of STERIS' test methodologies is made apparently without the knowledge of the methodologies or of the extensive body of data submitted to the EPA and FDA in support of STERIS' claims. Bond offers no definitive critique of why the test methodologies used are not adequate to support the conclusions drawn by Kralovic. The STERIS SYSTEM 1 Processor and STERIS 20 Sterilant were cleared for marketing in 1988. Independent testing of the system supports STERIS' claims. Why does Bond raise such issues in the context of Kralovic's article[2] on biological indicators? STERIS' data have been published and widely distributed for several years now. Does Bond have scientific data to support his concerns?

Bond takes issue also with instrument manufacturers. He believes that the complex, heat-sensitive medical instruments that are processed most commonly in liquid chemical systems contain components that are difficult, if not impossible, to clean and represent an unfair challenge even to the most powerful liquid chemical germicide system.[1] In fact, the issue of "design for cleanability" applies to the efficacy of steam and ethylene oxide sterilization as well as to liquid chemical systems for sterilization or disinfection. Much development work in the industry is ongoing to address the issue of making reusable medical instruments easier to clean and reprocess. STERIS is a leader in working with manufacturers through its Device Testing Program to sup port them in this development effort and the claims and instructions for reprocessing that they make.

It is difficult to understand the posture taken by Bond in his editorial statement made in the context of this peer-reviewed journal. Notwithstanding the lack of scientific data in his presentation, the message that he delivers misrepresents the efforts by STERIS and others to make possible higher standards of care.

As a final point, it is unusual that Kralovic's article, which was peer reviewed, should be prefaced with the negative editorial by Bond. Should not the issues raised

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by Bond have been raised in the review process or in a subsequent issue in response to the publication? Bond is not listed on the editorial board of *Infection Control and Hospital Epidemiology*. Whom do his comments represent? Should not scientific concerns be addressed by appropriate test data gathered in a scientific way and in a scientific forum?

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The author replies.

Opinions may differ based on a number of factors. However, there must be some degree of misunderstanding in Malchesky's response to my editorial. The use of biologic indicators designed for steam or ethylene oxide to monitor a liquid chemical sterilizer process has no precedent in the literature, and as such, the concept is open to question and concern. Further, Malchesky calls for specific data to justify my editorial position. The only such data are in corporate handout material or from other sources linked with vested commercial interests. The product-specific references listed in Kralovic's paper, in my editorial, and in Malchesky's reply to the editorial attest to this fact. Also, Malchesky should know that testing and evaluation of medical devices, other than in instances of ongoing disease outbreak investigations, is not in the mission function of the Centers for Disease Control and Prevention.

Malchesky mentions "much development work in the industry" toward resolution of current difficulties in instrument reprocessing. Apparently, details and results of such efforts are neither published nor distributed widely in the field. Herein is part of a major problem for medical device users. Until truly independent, unbiased data are forthcoming and are published in peer-reviewed journals, manufacturers' claims clearly will remain just that-claims. Appropriate studies in a number of areas could be made possible by, for instance, arrangement of carefully granted funds and supplies to a qualified and totally impartial academic institution. It is difficult to understand why this has not been done to date, especially for a product incorporating concepts as novel as the one represented by Malchesky.

In the interim, it is important to know that data submitted to federal regulatory agencies prior to marketing of a medical device do not necessarily reflect whether the device will work as expected in an in-use setting. With regard to my editorial questions about the unique methodologies allowed by regulatory federal agencies during pre-market testing of the medical instrument reprocessing system, it is also important to know that others recently have examined and questioned the entire process for federal registration, marketing clearance, and regulation of chemical germicides and related medical devices.[1,2] Interested readers may obtain single copies of these documents at no charge from the U.S. General Accounting Office, P.O. Box 6015, Gaithersburg, MD 20884-6015; telephone (202) 512-6000. At present, the user community will have little choice but to gather existing information and make individual decisions.

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The Editor replies.

In his final paragraph, Malchesky poses a series of questions that suggest an unfamiliarity with the traditions of this journal and, indeed, most medical journals. He states that publication of a "negative" editorial is "unusual." However, the editorials in four of the first eight issues of 1993 have criticized or taken issue with the related manuscript. As Malchesky notes, Bond is not on our Editorial Board; but then, neither has been any other editorialist this year.

Malchesky appears to be offended that the editorial contains opinion; but that is precisely its role. For each issue, we select the manuscript (even, rarely, a

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