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Keith S. Kaye, MD
Chair, Infection Control Committee
Co-Director Duke Infection Control Unit
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Dear Dr. Kaye:

The following is our report assessing the efficacy of sterilization processes when medical equipment is purposefully contaminated with high numbers of microorganisms, which is then overlaid with hydraulic fluid prior to sterilization.

Purpose: To determine if hydraulic fluid on surgical instruments alters the effectiveness of the sterilization process

Methods: Surgical instruments were inoculated with test microorganisms, coated with hydraulic fluid (provided by Duke University Medical Center), sterilized, and then cultured. Test items consisted of heat-resistant items (stainless steel knife handles) and heat-sensitive items (plastic syringe barrels) that were inoculated with ~2×10^6 *Staphylococcus aureus*, ~3×10^6 *Pseudomonas aeruginosa*, ~6×10^4 *Geobacillus stearothermophilus* spores or ~2×10^5 *Bacillus atrophaeus* spores. Following inoculation with the suspension of 10 µl of microorganisms, the carriers were allowed to air dry for 1 hour (knife handles) or 2 hours (plastic syringe barrels). The test item was then overlaid with the hydraulic fluid (20 µl) and placed in a peel pack or in a wrapped tray, and sterilized by either steam sterilization (prevacuum, 132°C for 4 minutes using a Steris Amsco Century V-120 Prevacuum Steam Sterilizer, Mentor, Ohio) or ethylene oxide sterilization (100% ETO using a Steris Amsco Eagle 3017 EO Sterilizer, Mentor, Ohio). After sterilization, each carrier was aseptically placed in a sterile test tube with 35 mL of trypticase soy broth (TSB) and allowed to shake for 1 hour. After shaking, each tube was vortexed and the TSB was filtered. In the final spore runs, the carriers were swabbed after the TSB was filtered, in order to verify that spores were not remaining adhered to the carriers. These swabs were then placed in 3 mL of TSB and incubated 48 hrs at 37°C or 53°C (depending on the spore used) along with the test filters, which were placed on sheep blood agar. The spores were also processed in an open, wrapped tray (1 run, 5 replicates) in order to verify that our test organisms were not removed via the process of being placed in peel packs.
Negative controls were performed by placing the inoculum on the carriers and allowing the inoculum to air dry. These carriers were then aseptically processed without the hydraulic fluid in order to verify that sterilization would normally be achieved. Positive controls were done as described above without being exposed to the sterilization process. This provided an estimate of the number of bacteria/spores present at the time of sterilization. These experiments were done from January 7, 2005 to April 27, 2005.

Results: Following sterilization, cultures of experimentally contaminated surgical instruments were negative (see Table).

Conclusion: In these laboratory experiments, we found that replacing cleaning detergent with hydraulic fluid did not alter the effectiveness of the sterilization process as high numbers of clinically-relevant bacteria and standard test spores (relatively resistant to the sterilization process) were completely inactivated. Our previous research has demonstrated that surgical instruments are most commonly contaminated with less than 100 vegetative bacteria (Am J Infect Control 1998;26:143). Thus, our recent experiments, which used much higher numbers of vegetative bacteria, provide assurance that infection would not result from instruments coated with hydraulic fluid and then sterilized. The use of high numbers of spores, which are relatively resistant to sterilization, further supports our conclusion that sterilization was not adversely affected by hydraulic fluid.

If there are any questions, please contact us.

Sincerely,

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Effect of Hydraulic Fluid on Steam and Ethylene Oxide Sterilization

Test Organisms	Method of Sterilization	Carrier Quantitation (Mean)	Number of Runs	No. of Positives / No. of Replicates
Geobacillus stearothermophilus spores	Steam Sterilization (Sterilization Pouch)	6.71×10^6 CFU/ml	6	0/21
	Steam Sterilization (Wrapped Open Tray)	6.15×10^6 CFU/ml	1	0/5
Methicillin-resistant *Staphylococcus aureus*	Steam Sterilization	2.24×10^8 CFU/ml	4	0/8
	Ethylene Oxide	2.25×10^8 CFU/ml	3	0/6
Pseudomonas aeruginosa	Steam Sterilization	3.50×10^8 CFU/ml	3	0/6
	Ethylene Oxide	2.99×10^8 CFU/ml	3	0/6
Bacillus atrophaeus spores	Ethylene Oxide (Sterilization Pouch)	2.34×10^5 CFU/ml	1	0/10
	Ethylene Oxide (Wrapped Open Tray)		1	0/5