The Q-Net Monthly

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What's New-

An article that discusses the reliability of different sterilization methods appears in this May's issue of the *AORN Journal*. And two letters to the editor that discuss liquid sterilants are published in April's *American Journal of Infection Control*.

Dates of Interest

- ✓ APIC's Conference: May 9th-13th, 1998; San Diego, CA.
- ✓ SGNA's Conference: May 16th-20th, 1998; Denver, CO.
- ✓ DDW's Conference: May 16th-20th, 1998; New Orleans, LA.

'Q-Net 97'



'Q-Net-97,' a bound collection of all of 1997's newsletters, is now available. Order your copy today for \$9.95 (includes S&H).

What is 'Q-Net'?

Q-Net is a technology-assessment network of questions and answers. Its newsletter is *7he* **Q-Net**TM*Monthly*.

Q-Net's main goal is to encourage the infection control and endoscopy communities to not only ask good questions but to also demand succinct and well referenced responses.

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

What is the AbTox Plazlyte[™] System?

~ This article discusses some of the safety issues surrounding a device designed to process items using a low-temperature vapor. ~

As the number of applications for reusable instruments damaged by heat continues to increase, so does the demand for lowtemperature sterilizing processes that are safe, effective, rapid-acting, inexpensive, and neither damage the instrument during processing nor leave toxic residues on the instrument after processing.

Developed as an alternative to ethylene oxide gas, the PlazlyteTM System ("PS") - manufactured by *AbTox Inc.* of Mundelein, IL - combines a low-temperature plasma with peracetic acid vapor. The plasma is produced by exposing a mixture of argon, hydrogen and oxygen to a electromagnetic field.¹

Several published reports have recently questioned the safety of the PS.²⁴ The April 24th (1998) issue of the *Morbidity* and Mortality Weekly Report indicates that use of the PS to process ophthalmic instruments caused 6 patients to develop corneal decompensation ("CD") (i.e., corneal edema and opacification) within 24 hours after eye surgery. The reported injuries occurred at the same medical center during the second week of January, 1998. After the facility replaced the PS with a steam autoclave, no additional cases of CD have been reported.

According to the Food and Drug Administration (FDA), a model of the PS

was cleared for marketing in 1994 (510[k] No: K905119). But *AbTox Inc.* did not distribute this model,² which had a chamber volume of 1 cubic-foot and was labeled for processing only stainless steel items lacking small hinges and lumens.

As discussed in a FDA Safety Alert,² *AbTox Inc.* distributed to health care facilities a modified model of the PS that the FDA considers to be substantially different from the original PS model that it "approved" for distribution in 1994. This modified model, which has a larger chamber volume (6 cubic feet) and uses a different gas mixture than the original PS model, has not been granted a 510(k) clearance by the FDA.²

Earlier this month, the FDA warned (Continued on page 8)



n the December 1997 issue of the Q-Net[™] Monthly, the properties of Sporox[®] (7.5% hydrogen peroxide) and Peract[™] 20 (a mixture of 0.08% peracetic acid and 1% hydrogen peroxide) were discussed. At that time, Minntech Corp. (Minneapolis, MN) was expected to market Peract[™] 20.

Earlier this year Advanced Sterilization Products (Irvine, CA, 800-595-0200), who markets the STERRAD,[®] announced it will market Peract[™] 20 under the new name of *Cidex[®] PA*.

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health care facilities that the PS may cause copper and zinc salts to form on ophthalmic instruments.² Copper compounds are injurious to human corneal endothelial cells, and therefore the FDA has concluded that patients could be injured by ophthalmic instruments (or any other instrument that contains copper, zinc, brass, or solder) processed by the PS.^{2,3} (*Note:* Brass is an alloy that primarily contains copper and zinc. And solder is a fusible alloy used to join metallic parts.)

Tests performed by the Centers for Disease Control and Prevention (CDC) identified copper and zinc in water that had been rinsed through the lumens of ophthalmic cannulae processed by the PS. According to the CDC, infusion of this effluent into human and rabbit corneas resulted in CD.⁴

MANUFACTURER'S RESPONSE

AbTox Inc. asserts that "no evidence has been presented that suggests a cause and effect relationship between the use of the PlazlyteTM sterilizer and post-operative complications."⁵ According to *AbTox, Inc.*, eye damage has also been reported "following surgery using instruments sterilized with steam and ethylene oxide gas." "To our knowledge, none of these reports have (*sic.*) attributed the problem to the sterilization process."⁵ Moreover, "no problems have been reported" from "literally thousands of surgical sets sterilized in the PS."⁵

RECOMMENDATIONS

The FDA has provided several recommendations:²

- Do not use the PlazlyteTM System to process ophthalmic (and other) instruments that contain copper, zinc, brass or solder. Remember that the distributed PS model has not received 510(k) clearance from the FDA;
- Before its reuse, thoroughly clean and resterilize (using an alternative process) any instrument that contains copper, zinc (or brass), or solder and may have been processed by the PS;
- Review and adhere to the instructions and labels of all sterilization processes - not just the PS process;[†]
- The reprocessing instructions of all instruments requiring sterilization (or disinfection) should also be reviewed to ensure their compatibility with the selected processing method. Contacting the instrument's manufacturer may

[†] Nota Bene: Although it has not determined whether the problem identified with the sterilization of ophthalmic surgical instruments is unique to the AbTox PlazlyteTM system, the FDA has not received reports linking "similar adverse events" to other processing systems that use peracetic acid, hydrogen peroxide, or plasma gas. be necessary to determine which sterilization (or disinfection) methods are - and which are not - recommended;

The CDC recommends that state health departments report each case of corneal decompensation following ophthalmic surgery, along with the type of sterilizer used to process the instruments, to the CDC's Hospital Infections Program, National Center for Infectious Disease (404) 639-6413, or the FDA's *MedWatch* program (800) 332-1088 (see Box, below).

REFERENCES

- 1 Bryce et al. Infect Control Hosp Epidemiol 1997;18(9):646-653.
- 2 Food and Drug Administration Safety Alert, dated 4-13-98: http:// www.fda.gov/cdrh/abtox.html.
- 3 The Boston Globe, April 3, 1998.
- 4 MMWR. 1998 April 24;47(15):306-309. 5 AbTox Inc.'s Letter to its Customers date
- AbTox Inc.'s Letter to its Customers, dated 3-4-98.

What is MedWatch?

The Safe Medical Devices Act of 1990 (SMDA) requires "hospitals and other user facilities" to report serious injuries and deaths that may have been - but were not necessarily caused by a medical device. Hospitals that do not consider an injury sufficiently serious to warrant filing a report, per SMDA regulation, can submit a voluntary report to: *MedWatch*, FDA, HFA-2 5600 Fishers Lane, Rockville, MD 20857-9787. FDA Safety Alerts can be viewed on the Internet at: www.fda.gov/cdrh/safety.html.

Thank you for your interest in this newsletter. I have addressed each issue to the best of my ability. Respectfully, the Publisher: Laurence 7. Muscarella, PhD. Please direct all correspondence to:

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