New Class 6 indicator monitors steam cycles

There's a new type of sterilization indicator on the block—the Class 6 emulating indicator. Steris recently received 510k clearance from the Food and Drug Administration to market the first Class 6 chemical indicators for steam sterilization in the US. The indicators are being sold under the brand name Verify SixCess. Class 6 indicators have been available for some time in Europe, Canada, and other parts of the world. Other companies are reportedly also planning to market Class 6 indicators in the US.

Steris says Class 6 indicators are a breakthrough because they allow for “immediate release of all sterilizer loads and provide a very high level of sterilization process assurance.” That means loads can be released “without the need to quarantine loads, use expensive readers, or complete emergency release documentation,” the company says.

Steris says the Class 6 indicators, which consist of a plastic strip with special yellow ink, “require the same critical parameters that are required to achieve the death of bacterial spores” plus a programmed safety margin. Class 6 indicators are matched to specific sterilization cycles, for example, a 270°F (132°C) 4-minute pre-vacuum cycle, a 270°F (132°C) 15-minute gravity cycle, and so forth. The indicators signify they have met the specified time and temperature parameters by a color change.

“These are all cycle specific, and each has its own 510k. Each is designed to monitor specific times and temperatures,” says Heide Ames, product manager for Steris. Steris received FDA clearance for 9 Class 6 indicator products for various times and temperatures, including flash sterilization.

Release of implants?

When Steris says its Class 6 emulating indicators allow “for the immediate release of all loads,” does that include implants?

“We don’t draw a distinction between implants and other items. We say they should all be sterile,” Ames says.

She acknowledged it will take time for professional standards and recommended practices to catch up with the technology.

Currently, the sterilization standard that ORs and sterile processing departments rely on, the Association for the Advancement of Medical Instrumentation (AAMI) Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities (ANSI/AAMI ST79:2006), does not include the Class 6 indicator. ST79 recommends monitoring every implant load with a biological indicator (BI) and quarantining the load until the BI results are available. AAMI says implant release before the BI results are available is “unacceptable,” and exceptions must be carefully defined, with documentation traceable to the patient. BIs are considered the “gold standard” of sterilization monitoring because they are the only indicator that directly measures the lethality of the sterilization process, AAMI notes.

The AORN sterilization recommended practices, revised for 2008, echo the AAMI recommendation for implants.

The Class 6 indicator is recognized in AAMI’s chemical indicator standard for manufacturers (ANSI/AAMI/ISO 11140-1). That standard defines Class 6 emulating indicators as “cycle verification indicators which shall be designed to react to all
critical variables for specified sterilization cycles. The SVs [stated values] are generated from the critical variables of the specified sterilization process.”

An AAMI working group is discussing how to recognize the Class 6 indicator in the AAMI ST79 standard, Ames notes. ST79 is reviewed annually, and AAMI will announce any updates. You can register to receive updates at www.aami.org/standards/st79.registry.html.

ST79 also contains a clause about new technology (page 81), noting that new sterilization monitoring devices may be cleared by the FDA, and health care facilities “should rely on their knowledge and expertise” in selecting and using new technology.

AAMI standards are available at www.aami.org.