3M's new quicker sterilization test could boost surgical safety

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The U.S. Food and Drug Administration gave 3M's new rapid sterilizing test kit the thumbs-up last month, meaning that hospitals can verify that surgical instruments are sterilized at low temperatures in just 24 minutes instead of the former four-hour time frame.

3M's new Attest Rapid-Readout Biological Indicator System is intended for sterilization processes that use vaporized hydrogen peroxide, or H2O2.

The new 24-minute test is a "quality assurance check" so health care facilities know their sterilization equipment is working properly. It gives "the fastest readout compared to any other FDA-cleared product on the market," said Ericka Lutz, 3M's global marketing manager for sterilization.

3M's Infection Prevention Division introduced the test in May at the International Association of Healthcare Central Service Materiel Management trade show. Since winning FDA clearance, it also has been showcased at health care conferences around the world.

"We've seen overwhelming market excitement about this system since we announced the 510(k) submission in May," Lutz said. "The common reaction we're hearing is, 'If our hospital is able to improve efficiencies and enhance patient safety, it's a clear win-win decision.'"

3M is no stranger to sterilization testing. If successful, the new processes

will help it capture a larger chunk of this $100 million market.

3M, based in suburban Minneapolis, spent years and significant research dollars trying to narrow the industry's test-time window. Last year, 3M launched its first system for vaporized H2O2 testing. It shrunk the testing period from the industry average of about 24 hours down to the four-hour period.

Armed with its new and better mousetrap, 3M will allow existing hospital customers to upgrade their old four-hour sterilization software to the new 24-minute system. Those upgrades will be done at no charge, Lutz said.

"We want all customers to be able to benefit from our innovation and use the speed of our system to help increase patient safety as fast as possible," she said.

Before getting into the hydrogen peroxide sterilization test business last year, 3M was already an industry leader in the more popular sterilization methods that use steam or ethylene oxide.

Currently, about 85 percent of all surgical instruments sterilization is done via steam sterilization, which is the fastest and the most cost-effective process. The remaining 15 percent of device sterilizations are done with the help of low temperature sterilization methods that use either ethylene oxide or vaporized hydrogen peroxide.

Hydrogen peroxide may be a well-known germ-killing staple in many household medicine cabinets, but it has been used at higher concentrations to kill germs in hospitals and clinics for 104 years. Vaporized H2O2 kills contaminants on surgical instruments by attacking spores, enzymes, nucleic acids, cell wall proteins, lipids and other molecular structures.

For decades, vaporized H2O2 and ethylene oxide were the method of choice for cleaning medical instruments that could not handle extremely high temperatures or excessive moisture. These sensitive instruments often had embedded electronics or other complexities and included surgical cameras, robotic equipment and endoscopes, 3M officials said.

With last year's entry and this year's improvements with vaporized H2O2 sterilization tests, 3M expects to grow its business dramatically. 3M currently has about 2,000 hospital customers using its vaporized H2O2 testing kits.

"3M hopes to provide the confidence and peace of mind to the VH2O2 method of sterilization similar to what has been created over the last 25 years for steam and ethylene oxide sterilization," Lutz said. "The new product will enable growth of (3M) sales in the existing VH2O2 market, as well as enable hospitals to practice more frequent monitoring due to the shortened readout. With only a 24-minute incubation for biological indicators, customers are able to get the biological indicator readout and quarantine (any tainted) instruments before releasing them for use in surgery. ... Running more frequent biological indicators helps to improve patient safety, keep the (hospital's) Central Sterile Department efficient and help operating rooms stay on schedule."

Larry Talapa, a microbiologist in 3M Healthcare's Infection Prevention Division, said in a recent research report that "it is likely that low-temperature sterilization will continue to grow because more and more critical and semi-critical reusable medical devices are made of materials and components that cannot withstand the high temperature and moisture in steam sterilization processes."

The ultimate goal, he said, is to minimize the risk of surgical site infections by destroying all microorganisms on the devices before they are reused.