



June 4, 2009

Dear Valued Customer,

The safety and well-being of all users of Kimberly-Clark products is of paramount importance to us. We want to provide you with an update regarding the KIMGUARD* Sterilization Wrap product lines.

Due to the changing regulatory environment, Kimberly-Clark Health Care (KCHC) collaborated with the Food and Drug Administration (FDA) to provide updated test data to the FDA for the KIMGUARD Sterilization Wrap products. The most recent FDA Draft Guidance for sterilization packaging, which though labeled as a draft is stringently followed by the FDA in reviewing new product marketing submissions, was used to determine the testing methodologies¹.

The FDA Draft Guidance calls for different testing protocols than KCHC previously performed on the KIMGUARD Sterilization Wrap. Notably, the FDA now requires Maintenance of Package Integrity (MPI) testing for all sterilization packaging products. The MPI protocol incorporates both events and time together to determine the integrity of the sterilized package.

KCHC had previously tested event-related sterility maintenance separate from time-related sterility maintenance. In fact, time-related sterility maintenance had been completed up to one year, but without the event-related portion of the MPI study. The more vigorous MPI test combines the two tests into a single protocol. Therefore, KCHC will need to repeat all testing previously completed on the KIMGUARD Sterilization Product lines to comply with the new more stringent FDA requirements.

Rest assured there have been no changes to the KIMGUARD product lines in over five years, just the testing protocols. And at no time has the FDA required KCHC to stop marketing or selling the KIMGUARD product lines.

Below are answers to frequently asked questions:

Why does the 510(k) summary state that the Sterilization Wrap shelf life is 30 days post sterilization?

- Historically, KCHC has advocated event-related sterility.
- The FDA required KCHC to adhere to the most recent FDA Draft Guidance when recently updating the 510(k) market clearance for KIMGUARD Sterilization Wrap¹. This guidance requires all sterilization packaging to address both event- and time-related sterility maintenance.
- KCHC is the first sterilization wrap manufacturer to adhere to the FDA's current requirement for an event- and time-related sterility maintenance study that is published in the manufacturer's 510(k) Summary.
- The FDA does not dictate the length of study required to establish the time portion of the study, but they do require that a time be specified. When KCHC was prepared to file the 510(k) updates, 30 day shelf life testing had been completed.
- Additional testing will be conducted at 6 months and one year of combined time- and event-related sterility. This testing is conducted in real time, and cannot be accelerated.

- During this transition period, hospitals should continue their current practices and protocols. Once KCHC has completed all testing, and the FDA has cleared the additional submissions, KCHC will assist customers in updating the facility protocols.

Why does the 510(k) summary state KC300 Model KIMGUARD ONE-STEP* Sterilization Wrap is not indicated for use for the pre-vacuum steam sterilization?

- The FDA requires 100% negative growth results in the Maintenance of Package Integrity (MPI) test. In this test, the gauze is removed after the package is opened and handled by technicians. Contamination leading to “false” positives could occur during the package presentation or while transferring the gauze to the test media. We believe this is what happened during our KC300 ONE-STEP wrap testing because of investigation findings into the circumstances of the microbial growth.
- All other ONE-STEP and Sequential grades of KIMGUARD wrap passed the MPI test for both pre-vacuum steam and EO.
- KC300 was retested, passed, and the additional data is being submitted to the FDA with the goal of expanding the marketing clearance to include KC300 for pre-vacuum steam sterilization.

Why were STERRAD® Sterilization Systems not mentioned in the Indications for Use?

- KCHC has not validated KIMGUARD in STERRAD Systems.
- Advanced Sterilization Process (ASP), the manufacturer of STERRAD Systems, recommends polypropylene wrap for all STERRAD Systems. All KIMGUARD products are polypropylene wrap.
- According to an ASP communication to its customers, “Kimberly-Clark* wrap products were used in all sterility validation tests using wrap to validate the STERRAD Systems for 510(k) clearance with the Food and Drug Administration (FDA).”
- KCHC and ASP are working together to validate the KIMGUARD brand of polypropylene wrap for use in the STERRAD Systems, and to submit a 510(k) marketing clearance submission to the FDA specifically supporting KIMGUARD wraps in the STERRAD Systems.

Kimberly-Clark is committed to providing safe, effective products for our customers, and we are confident in the quality of our sterilization wrap products.

If you have questions or would like to discuss further, please call your Kimberly-Clark Sales Representative, or 1-800-742-1996.

Regards,

Jay Hexamer
General Manager, North America Sales and Marketing
Medical Supplies

¹ “Premarket Notification [510(k)] Submissions for Medical Sterilization Packaging Systems in Health Care Facilities; Draft Guidance for Industry and FDA” dated March 7,2002 (<http://www.fda.gov/cdrh/ode/guidance/1388.pdf>)