



August 10, 2009

Dear Valued Customer:

The purpose of this communication is to provide information. No action is required.

Kimberly-Clark Health Care (KCHC) has been working with the Food and Drug Administration (FDA) to provide guidance around information contained in the recent 510(k) clearances for the KIMGUARD\* Sterilization Wrap product line. Specifically, there has been confusion around the following statement: *“The Wrap has also been tested for the ability to maintain sterility of pack contents after sterilization for up to 30 days under standard conditions.”*

**It was not the intention of the FDA for customers to add expiration dates to sterilized packages.**

Rather, the FDA is requiring all sterilization packaging manufacturers to provide Directions for Use (DFU) that include the length of time Maintenance of Package Integrity testing has been completed.

Therefore, KCHC has worked with the FDA to develop language that will inform customers of the completed testing without requiring changes to hospital practices and protocols. This language will be included in the DFU KCHC will be including in every case of KIMGUARD\* Sterilization Wrap.

Within the next month, KCHC expects all language in the DFU to be finalized. At that time, your Kimberly-Clark Sales Representative will meet with each customer to review the information. Customers should expect to see the DFU in the product in the fourth quarter of this year.

**IMPORTANT:** Since there is no clinical evidence to necessitate a change to hospital practices and protocols around sterility maintenance, hospitals should continue to follow their existing practices and protocols.

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