

# Kimberly-Clark Health Care Receives FDA Clearance For KIMGUARD ONE-STEP Sterilization Wrap Portfolio With One-Year Maintenance Of Package Integrity And Amsco V-PRO MaX (Flexible Cycle)

## **-All grades of ONE-STEP Wrap are now FDA-cleared for use with all three Amsco V-PRO Sterilization Systems-**

ROSWELL, Ga., July 12, 2012 /PRNewswire/ -- [Kimberly-Clark Health Care](#) announced today that it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) to market the KIMGUARD ONE-STEP portfolio with one-year maintenance of package integrity (MPI) for KC300 to KC600 for Pre-vacuum Steam and Ethylene Oxide (EO). Users can now have confidence that their instruments wrapped with KIMGUARD ONE-STEP Sterilization Wrap will maintain sterility on the shelf for at least 365 days.

The KIMGUARD family of sterilization wrap is now the most validated sterilization wrap with the longest shelf-life on the U.S. market. These additional clearances will assist facilities in complying with The Joint Commission's sterilization processing guidelines.

"We are the only manufacturer with sterilization wraps that has been validated and FDA cleared for at least 365 days post-sterilization processing shelf-life. In fact, KIMGUARD ONE-STEP shelf-life is currently 12 times longer than any other sterilization wrap's shelf-life that has been previously cleared and marketed. This is especially significant for surgical trays that aren't used on a regular basis," said Tom Gonzalez, VP Quality Assurance & Regulatory Affairs, Kimberly-Clark Health Care.

"The extensive testing conducted to obtain MPI one-year 510(k) clearance illustrates Kimberly-Clark's commitment to providing our customers with sterilization solutions that meet their needs while offering the optimum balance of properties including lint and flame resistance, and high bacterial filtration efficiency (BFE), to provide our customers with confidence in sterility," added Mr. Gonzalez.

With the most recent FDA clearance for Amsco V-PRO maX Low Temperature Sterilization System (Flexible Cycle), the KIMGUARD ONE-STEP Sterilization Wrap is now FDA cleared for use with all cycles in the three Amsco V-PRO Sterilization Systems. With this announcement, KIMGUARD Sterilization Wrap has the most 510(k) clearances than any other sterilization wrap including use with:

- Pre-vacuum Steam - up to 1 Year MPI
- Ethylene Oxide (EO) - up to 1 Year MPI
- Amsco V-PRO maX (V-PRO Lumen, Non Lumen and Flexible Cycles)
- Amsco V-PRO 1 Plus (V-PRO Lumen and Non Lumen Cycles)
- Amsco V-PRO 1 (V-PRO Lumen Cycle)

These are some of the commonly used sterilization modalities, making One-Step the most widely compatible sterilization wrap on the market.

Kimberly-Clark has also completed testing that supports use of KIMGUARD ONE-STEP Sterilization Wrap with additional low temperature sterilization systems. This data has been submitted to the FDA for acceptance.

### **Confidence with KIMGUARD ONE-STEP**

KIMGUARD ONE-STEP Sterilization Wrap consists of two layers of wrap thermally sealed along the sides to provide protection of double-wrapping in one step. This feature cuts the wrapping and unwrapping time in half compared to sequential wrapping, saving valuable time in Sterile Processing, as well as sterility assurance in the operating room (OR). The most recent addition to the KIMGUARD ONE-STEP Wrap portfolio, QUICK CHECK Sterilization Wrap, securely joins a blue wrap layer with a white layer so users can quickly and easily identify if sterility has been breached - ensuring patient safety. In addition, KIMGUARD Sterilization Wrap, manufactured in the US, features PowerGuard Technology to provide superior protection against contamination, making it one of the best microbial barriers available.

### **Commitment to Managing Wrap Waste**

Launched earlier this year, Kimberly-Clark Health Care offers a wrap recycling program called Blue ReNew to bring interested hospitals a systematized approach to wrap recycling. The program is designed to help hospitals organize the process of recycling their wrap into five achievable stages and can be customized to meet the specific needs of each facility. The Kimberly-Clark Blue ReNew Team works with hospitals to identify key recycling partners, train OR teams and measure results to achieve a sustainable wrap recycling program.

### **Kimberly-Clark in the Healthcare Environment**

Around the world, medical professionals turn to Kimberly-Clark Health Care for a wide portfolio of solutions that improve the health, hygiene and well-being of patients and hospital staff. As part of their healing mission, caregivers rely on Kimberly-Clark Health Care to deliver clinical solutions and educational resources that they can depend on to prevent, diagnose and manage a wide variety of healthcare-associated infections. As a global enterprise with more than \$1 billion in annual sales, Kimberly-Clark Health care holds the No. 1 and No. 2 market share positions in several categories including; infection control solutions, surgical solutions, pain management and digestive health. Throughout the care continuum, patients and staff alike trust Kimberly-Clark medical supplies and devices, KLEENEX tissues, Kimberly-Clark Professional skin care products and SCOTT towels for day-to-day needs. For more information, please visit <http://www.kchealthcare.com>.

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