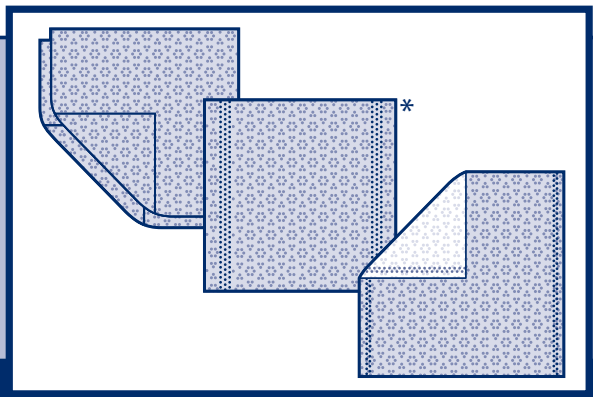
Kimberly-Clark*

*Kim*Guard*
Sterilization Wrap
*Kim*Guard One-Step*
Sterilization Wrap
*Kim*Guard One-Step*
Quick Check* Sterilization Wrap



Instructions for Use

Models:

KC**100**
KC**200**
KC**300**
KC**400**
KC**500**
KC**600**

This booklet contains additional information required for distribution of this product in the United States.*

Single Use Only

Disposable

Product Description

Kimguard* Sterilization Wrap is supplied to the customer as bulk packages of single sheets, where in accordance with standard hospital practices, two sheets are then used to wrap a medical device or a collection of medical devices for sterilization. Kimguard One-Step* Sterilization Wrap and Kimguard One-Step* Quick Check* Sterilization Wrap are comprised of two sheets of Kimguard* Sterilization Wrap ultrasonically seamed on two sides. This allows for convenient wrapping with two sheets simultaneously.

The sheets of sterilization wrap are square or rectangular fabric produced using a three-layer SMS (spunbond-meltblown-spunbond) process. The wrap fabric is composed of polypropylene with the addition of less than 2% by weight of phthalocyanine blue pigment, less than 1% by weight of titanium dioxide pigment, and less than 0.009% by weight of a potassium phosphate anti-static treatment. The wrap allows a sterilized package to be opened aseptically.

Kimguard*, Kimguard One-Step* and Kimguard One-Step* Quick Check* Sterilization Wraps are available in various sizes (dimensions of sheet) including those offered in Table 1.

Table 1. Dimensional Specifications of the Wraps

Dimensions	KC100	KC200	KC300	KC400	KC500	KC600
9 in. x 9 in.	x					
12 in. x 12 in.	x	x				
15 in. x 15 in.	x	x				
18 in. x 18 in.	x	x	x	x	x	
20 in. x 20 in.	x					
24 in. x 24 in.	x	x	x	x	x	
30 in. x 30 in.	x	x	x	x (Kimguard*)	x	
36 in. x 36 in.	x	x	x	x	x	x
40 in. x 40 in.	x	x	x	x		x
45 in. x 45 in.	x		x	x	x	x
48 in. x 48 in.	x	x	x	x	x	x
54 in. x 54 in.	x	x	x	x	x	x
60 in. x 60 in.					x	
54 in. x 72 in.	x	x	x	x	x	x
54 in. x 90 in.					x	

Indications for Use

Kimberly-Clark* Sterilization Wraps are intended to be used to enclose another medical device that is to be sterilized by a health care provider by pre-vacuum steam at 270ºF/132ºC for 4 minutes or by 100% ethylene oxide (EO) with a concentration of 725-735 mg/L at 131°F/ 55ºC and 40% - 80% relative humidity for 60 minutes. Kimguard One-Step* and Kimguard One-Step* Quick Check* Sterilization Wraps are also intended to be used in the Amsco® V-PRO™ 1 Low Temperature Sterilization System's cycle and the Amsco® V-PRO™ 1 Plus Low Temperature Sterilization System's Lumen (identical to the V-PRO™ 1 Cycle) and Non Lumen Cycles. The wrap is intended to allow sterilization of the enclosed medical device(s) and also to maintain sterility of the enclosed device(s) until opened. The wrap was validated for aeration times for EO sterilization of 8 hours at 55ºC or 12 hours at 43.3ºC. The Kimguard* Sterilization Wrap, Kimguard One-Step* Sterilization Wrap and Kimguard One-Step* Quick Check* Sterilization Wrap were validated for dry times for pre-vacuum steam sterilization of 20 minutes for Models 100 and 200, and for 30 minutes for Models 300, 400, 500, and 600. The Kimguard One-Step* Sterilization Wrap and Kimguard One-Step* Quick Check* Sterilization Wrap were validated to be effectively aerated during the pre-programmed V-PRO™ 1 and V-PRO™ 1 Plus Sterilization Cycles.

Kimguard*, Kimguard One-Step* Sterilization Wrap and Kimguard One-Step* Quick Check* Sterilization Wrap are not indicated for use for gravity steam sterilization.

Warnings

- When utilizing a 100% ethylene oxide (EO) sterilization cycle with a concentration of 725–735 mg/L at 131°F/ 55ºC and 40%–80% relative humidity for 60 minutes with the Kimguard*, Kimguard One-Step* Wrap and Kimguard One-Step* Quick Check* Sterilization Wrap, do not sterilize at a set point below 131°F/ 55ºC. Ensure that the conditioning phase of the cycle is at 131°F/ 55ºC for at least 30 minutes.
- Do not use wrap for the following sterilization methods:
  - dry heat
  - radiation (such as gamma, E-beam, or other radiation methods)
  - gravity steam
- Do not use wrap if damage or extraneous matter is detected prior to use.
- Do not use wrapped contents if wrap is torn, wet, or compressed.

Precautions

- Do not open case or package with a sharp knife. Knives can easily cut the wrap.
- Prior to use, assure that all medical devices intended to be sterilized while wrapped within the Kimberly-Clark* Sterilization Wraps are compatible with and sterilizable by the sterilization modality and cycle listed in the Indications for Use in these directions. Consult the sterilization instructions for all devices intended for sterilization. Some medical devices, regardless of the sterilization method and sterilization wrap/container used, may require special consideration in packing configurations to ensure sterilization, as is the case with some fluid-resistant linens (refer to Section 8.3.5 ANSI/AAMI ST79 *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities*).
- Do not use in the presence of flammable anesthesia. The wrap is non-conductive.
- If sterilization is performed by an outside contract facility, Kimberly-Clark recommends that the wrapped devices should be protected from contamination by an additional covering.

Instructions for Use

The Kimguard*, Kimguard One-Step* and Kimguard One-Step* Quick Check* Sterilization Wraps should be used in accordance with the preparation, wrapping, and sterilization chamber loading recommendations of the following standards:

- ANSI/AAMI ST79: *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities*
- ANSI/AAMI ST41: *Ethylene Oxide Sterilization in Health Care Facilities*
- AORN Standards, Recommended Practices, and Guidelines

Storage Prior to Use

- Location should be
  1) clean
  2) dust free
  3) away from fluorescent or ultraviolet light
- Use first in, first out (FIFO) stock rotation.

Prior to Use

- Condition wraps at ideal temperature and humidity for a minimum of two hours.
  - Temperature 68°F to 73°F / 20°C to 23°C
  - Relative humidity ranging from 30% to 60%
- Examine wrap and discard if damage or extraneous matter is detected.
- Thoroughly clean and dry items to be wrapped/packaged.

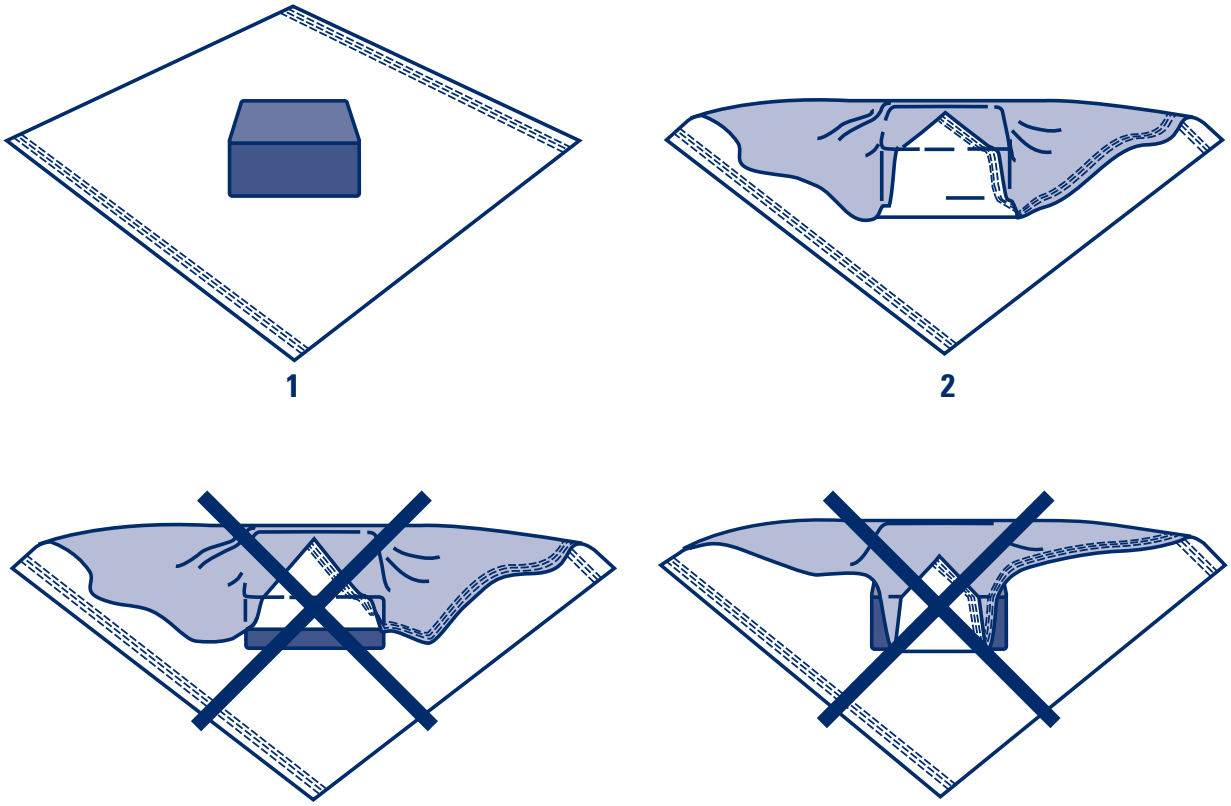
Wrapping with Kimguard* Wrap: Common Double Sequential Wrapping Techniques[1,2]

- Place item(s) on one sheet and wrap using typical aseptic wrapping technique. Recommendations for wrap contents are provided in Table 2 (Pre-Vacuum Steam/Ethylene Oxide) and Table 3 (V-PRO).
- Place this wrapped "package" on a second sheet and wrap again.
- Securing the Wrapped Package:
  - Secure with a common closure (tape or alternate closure suitable for the sterilization method to be used) and label.
  - Closure must
    1) allow the sterilant to penetrate the wrapped package
    2) avoid constriction of the package
    3) maintain package integrity
- Label the wrapped package with the statement "Sequentially Wrapped."

[1]ANSI/AAMI ST79: *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities*
[2]AORN Standards, Recommended Practices, and Guidelines

Wrapping with KIMGUARD ONE-STEP* and KIMGUARD ONE-STEP* QUICK CHECK* Wraps: Common Double Simultaneous Wrapping Techniques[1,2]

- Place item(s) on the double-sheet and wrap using typical aseptic wrapping technique. Recommendations for wrap contents are provided in Table 2 (Pre-Vacuum Steam/Ethylene Oxide) and Table 3 (V-PRO).
- Ensure that the first fold is pulled far enough to cover all package contents. The correct first fold is demonstrated below in Diagram 2. Incorrect folds, where the first fold is not pulled far enough to cover all package contents, are pictured in the diagrams marked with an "X." **Caution: Covering all package contents with the first fold is required for sterility maintenance, and failure to follow this correct wrapping technique could compromise sterility.**



Demonstrating Proper vs. Improper First Folds for Double Simultaneous Wrapping (Diagram 1 shows the contents situated on the double wrap prior to folding, while Diagram 2 shows a correct first fold.)

- Securing the Wrapped Package:
  - Secure with a common closure (tape or alternate closure suitable for the sterilization method to be used) and label.
  - Closure must
    1) allow the sterilant to penetrate the wrapped package
    2) avoid constriction of the package
    3) maintain package integrity
  - Label the wrapped package with the statement "KIMGUARD ONE-STEP* – Open Once".

[1]ANSI/AAMI ST79: *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities*
[2]AORN Standards, Recommended Practices, and Guidelines

Table 2: Wrap Model Recommendations for Pre-Vacuum Steam and for 100% Ethylene Oxide Sterilization[1]

All Kimberly-Clark* Sterilization Wrap Models	Intended Loads	Maximum Wrapped Package Content Weights Used in Sterility Maintenance Validation Study[2]	Descriptions of Loads Used in Sterility Maintenance Validation Study[2]
KC**100**	Very Light Weight Package (for example: towel packs)	3 lbs.	16 huck towels (17 in. x 29 in.)
KC**200**	Light Weight Package (for example: standard linen packs)	6 lbs.	2 huck towels (17 in. x 29 in.) 2 fluid-resistant U-drapes (68 in. x 109 in.) 1 fluid-resistant universal bar drape (70 in. x 108 in.)
KC**300**	Light to Moderate Weight Package (for example: general use medical instruments)	9 lbs.	**For Pre-Vacuum Steam:** 15 huck towels (17 in. x 29 in.) 1 small fluid-resistant drape (60 in. x 76 in.) 5 lbs. of metal mass **FOR EO:** 16 huck towels 2 fluid-resistant large drapes (76 in. x 100 in.) 1 fluid-resistant small drape (76 in. x 60 in.) 1 fluid-resistant table cover (60 in. x 90 in.)
KC**400**[3]	Moderate to Heavy Weight Package (for example: general use medical instruments)	13 lbs.	4 tray liners (20 in. x 25 in.) stacked 10 in. x 10 in. x 3 ½ in. tray containing 11 lbs. of metal mass
KC**500**[3]	Heavyweight Package (for example: general use medical instruments)	17 lbs.	4 tray liners (20 in. x 25 in.) stacked 10 in. x 10 in. x 3 ½ in. tray containing 15 lbs. of metal mass
KC**600**[3]	Very Heavy Weight Package (for example: general use medical instruments)	25 lbs.	4 tray liners (20 in. x 25 in.) stacked 10 in. x 10 in. x 3 ½ in. tray containing 23 lbs. of metal mass

Table 3: Wrap Model Recommendations for Amsco V-PRO 1 and V-PRO 1 Plus Low Temperature Sterilization[1]

Kimguard One-Step* and Kimguard One-Step* Quick Check* Sterilization Wrap Models	Intended Loads	Maximum Wrapped Package Content Weights Used in Sterility Maintenance Validation Study[2]	Descriptions of Loads Used in Sterility Maintenance Validation Study[2]
KC**100**	Very Light Weight Package (for example: batteries)	3 lbs.	3 lbs. metal mass 6 forceps
KC**200**	Light Weight Package (for example: telescope with light cord)	6.5 lbs.	2.5 lbs. metal mass 6 forceps V-PRO tray (17" x 10" x 3½") at 4 lbs.
KC**300**	Light to Moderate Weight Package (for example: general use medical instruments)	9 lbs.	5 lbs. metal mass 6 forceps V-PRO tray (17" x 10" x 3½") at 4 lbs.
KC**400**	Moderate to Heavy Weight Package (for example: general use medical instruments)	10 lbs.	6 lbs. metal mass 6 forceps V-PRO tray (17" x 10" x 3½") at 4 lbs.
KC**500**[4]	Heavyweight Package (for example: general use medical instruments)	10 lbs.	5 lbs. metal mass 6 forceps V-PRO tray (21" x 10" x 3½") at 5 lbs.
KC**600**[4]	Very Heavy Weight Package (for example: general use medical instruments)	10 lbs.	5 lbs. metal mass 6 forceps V-PRO tray (21" x 10" x 3½") at 5 lbs.

[1] Individual results may differ due to factors such as variations in handling practices, wrapping techniques, and folding methods. Results may also differ due to the use of irregularly shaped contents, which may put added stress on the wrap. Each healthcare facility should determine for itself which wrap model is most appropriate for each intended use.

[2] It is recommended to not exceed the maximum wrapped package content weights indicated for each wrap model. Furthermore, it is recommended to not exceed the number, weight, and size of individual content types that were validated for the Kimguard*, Kimguard One-Step* and Kimguard One-Step* Quick Check* Sterilization Wraps (i.e., the number and size of the fluid-resistant linens or the weight of the metal mass).

[3] The KC400, KC500, and KC600 model wraps were validated for sterilant penetration with 3 lbs. of non-fluid resistant linen, and it is recommended to not exceed 3 lbs. of non-fluid resistant linen in sterilization cycles with these models. It is recommended that the user not include fluid-resistant linens in KC400, KC500, and KC600 model wraps, as use of such fluid-resistant materials has not been evaluated with these models.

[4] The KC500 and KC600 Kimguard One-Step* and Kimguard One-Step* Quick Check* Sterilization Wraps models should be used only with the 21 inch x 10 inch V-PRO 1 tray.

Sterilization

- Kimguard*, Kimguard One-Step* and Kimguard One-Step* Quick Check* Sterilization Wraps are intended for use with the common healthcare sterilization parameters listed in the Indications for Use. The sterilizer manufacturer should be consulted for appropriate sterilizer loading configurations.
- If a sterilizer malfunctions or a cycle is aborted before completion, packages wrapped with Kimguard*, Kimguard One-Step* and Kimguard One-Step* Quick Check* Sterilization Wraps should be re-wrapped prior to being placed into another sterilization cycle.
- Results of an Ethylene Oxide Residuals Study are available upon request.
- In a Maintenance of Package Integrity Study for pre-vacuum steam sterilization using the content recommendations in Table 2, the Kimguard*, Kimguard One-Step* and Kimguard One-Step* Quick Check* Sterilization Wraps were validated for dry times for pre-vacuum steam sterilization of 20 minutes for Models 100 and 200, and for 30 minutes for Models 300, 400, 500, and 600. Study reports are available upon request. ***Note:*** *Many factors can affect drying time other than sterilization wrap, including but not limited to: the pack configuration that is used, cycle variations, the performance of the sterilizer machine, temperature distribution, steam generation, altitude, and ambient temperature and humidity.* Sterilizers vary widely in design and performance characteristics. As recommended in the ANSI/AAMI guidelines on steam sterilization, the user should consult the sterilizer manufacturer's operator manual for specific drying times.

Post-Sterilization Cooling/Unloading

- Leave wrapped packages on the sterilizer cart untouched until cool to avoid compromising package sterility.
- Visually inspect wrapped items as they are removed from the cart. Items that are torn, wet, or compressed should not be used.
- Packages are ready for immediate unloading if sterilized in the Amsco V-PRO 1 or V-PRO 1 Plus Low Temperature Sterilization Systems (Note: Applies to Kimguard One-Step* and Kimguard One-Step* Quick Check* Sterilization Wraps only).

Sterility Maintenance

- Healthcare facilities may use established protocols to monitor sterility maintenance of packages wrapped with the Kimguard* and Kimguard One-Step* Sterilization Wraps in accordance with accepted standards of practice. Real-time testing simulating clinical use supports maintenance of package sterility for at least 30 days; however, this time-point does not prevent facilities from continuing to use established healthcare facility protocols.
- Store wrapped packages as recommended in the ANSI/AAMI and AORN guidelines.
- Location should be
    1) clean
    2) dust free
    3) away from fluorescent or ultraviolet light
- Ideal storage parameters:
    - Temperature 68°F to 73°F / 20°C to 23°C
    - Relative humidity ranging from 30% to 60%
- Use first in, first out (FIFO) stock rotation.
- **Caution: Do not stack trays. Stacking trays can result in damage to the wrap caused by undue pressure from the weight.**

Opening

- Inspect package for damage, wetness, or any sign of potential contamination prior to opening and again after opening but before use of contents. **Caution: Do not use contents if these conditions are present, as sterility could be compromised.** Reprocess the contents using an unprocessed wrap if any of these conditions are noted.
- Open packages aseptically in accordance with the health facility's policy.

Disposal

- Do not re-use. Kimberly-Clark does not endorse the re-use (re-sterilization) of its sterilization wraps and does not warrant performance if product is re-used.
- Landfill or incinerate based upon state and local regulations.
- The wrap is composed of polypropylene plastic which has a plastics recycling code of "5."

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