Instructions for Use: SafeGuard Dry Sterilization Wrap

Brand Name of Product: SAFEGUARD DRY
Generic Name of Product: Sterilization Wrap

Product Description
The SafeGuard Dry Sterilization Wraps are square nonwoven sheets produced consisting of two layers of nonwoven ultrasonically bonded together along two edges for convenient simultaneous wrapping of one or a collection of medical devices that will be sterilized following standard healthcare practices. The wraps consist of two distinct nonwovens for each layer.

Outer Layer: SMS nonwoven layer produced using a spunbond-meltblown-spunbond process and composed of polypropylene with blue or green pigment and an anti-static treatment.

Inner Layer: Wetlaid nonwoven produced using a wood pulp process which is composed of natural wood pulp and synthetic fibers bonded with a synthetic binder containing blue or green pigment and treated to impart hydrophilic properties.

SafeGuard Dry wraps allow a sterilized package of medical devices to be opened aseptically and supplied in a variety of sheet sizes ranging from 24"x24" to 54"x54". The sterilization wraps have no intended patient contact and are supplied non-sterile. They are for single use.

Indications for Use
Healthmark SafeGuard Dry Sterilization Wraps are intended to be used to enclose another medical device that is to be sterilized by a healthcare provider via the following:

- Pre-vacuum Steam 270°F/132°C for 4 minutes
  - Dry time of 20 minutes for SafeGuard Dry Heavy
- 100% Ethylene Oxide (EO) with a concentration of 725-759 mg/L @ 131°F/55°C and 40% - 70% relative humidity for 60 minutes
  - Aeration time of 8 hours at 55°C

Table 1: SafeGuard Dry Models and Load Recommendations

		Wrap Sheet Size (in), Maximum Recommended Wrapped Package Content Weight: Pre-Vacuum Steam and Ethylene Oxide					
Grade	**Intended Load**	**24x24**	**36x36**	**40x40**	**45x45**	**48x48**	**54x54**
Heavy	Very Heavy weight package (e.g. general use medical instruments)	6.4 lb	14.2 lb	17.5 lb	22.1 lb	25 lb	25 lb

Table 2: SafeGuard Dry Wrap Models, sheet color

SafeGuard Dry Grade	**Wrap Layer**	**Individual Sheet Color**
Heavy	Outer Layer	Dark Blue
	Inner Layer	Green

Storage Prior to Use
Storage location should meet the following conditions: 1) Clean; 2) Free of Dust; 3) Away from fluorescent or ultraviolet light

Prior to Use

- Recommended temperature and humidity conditions: 1) Temperature (68°F to 73°F)/(20°C to 23°C); 2) 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.

Steps for Use of Product

SafeGuard Dry 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

Common Simultaneous Double Wrapping Technique

- Place sheet of wrap on flat surface with SMS Outer layer (Blue) on bottom touching the flat surface. The cellulose inner wrap layer (Green) should be on top.
- Place item(s) on the cellulosic Inner wrap layer (Green) and wrap using typical aseptic wrapping technique per ANSI/AAMI ST79 and CDC guidelines. Recommendations for wrap contents are provided in Table 1
- Ensure that the first fold is pulled far enough to cover all package contents.

Caution: Covering all package contents with the first fold is required for sterility maintenance, and failure to follow this for correct wrapping technique could compromise sterility.

- Securing the Wrapped Package:
    - Secure with an appropriate closure (tape or alternate closure suitable for the sterilization method to be applied) and label.
    - Closure must: 1) Allow the sterilant to penetrate the wrapped package; 2) Avoid constriction of the package; 3) Maintain package integrity.

Special Warnings and Cautions

Warnings:

- Do not apply wrap to the following sterilization methods: 1) Dry Heat 2) Radiation 3) Chemical Vapor 4) Hydrogen Peroxide
- Inspect wrap for damage or extraneous matter prior to use. If a defect is detected, do not use.
- Do not use wrapped contents if wrap is torn or wet.
- Do not re-use sterilization wraps

Precautions:

- Do not open carton or package with a sharp knife, knives can easily damage the wrap.
- Prior to use, assure that all medical devices intended to be sterilized while wrapping within SafeGuard Dry Sterilization Wraps are compatible with and sterilizable by the sterilization modality and cycle listed in the Indications for Use within these instructions. Consult the sterilization instructions for all devices intended for sterilization. Some medical devices, regardless of the sterilization method and sterilization wrap/container applied, may require special consideration in packing configurations to ensure sterilization. Some of these considerations are referenced in ANSI/AMI ST79 Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities.
- Do not use in the presence of flammable anesthesia.
- If sterilization is performed by an outside contract facility, Healthmark recommends that the wrapped devices be protected from contamination by an additional covering.
- Complex instruments (e.g., air-powered instruments, endoscopes, and instruments with lumens, hinges or knurls) should be prepared and sterilized in accordance with instrument manufacturer's instructions.

Disposal

- Do not re-use SafeGuard Dry Sterilization Wrap. Healthmark does not endorse the re-use (re-sterilization) of its sterilization wrap and does not warrant performance if product is re-used.
- Recycle, landfill or incinerate used wrap based upon state and local regulations.

Sterilization

- SafeGuard Dry Sterilization Wraps are intended for use with the common healthcare sterilization parameters described in the Indications for Use. Users should consult the sterilizer manufacturer for appropriate sterilizer loading configurations.
- If a sterilizer malfunctions or the full cycle is not completed for any reason, packages should be re-wrapped with an unprocessed SafeGuard Dry wrap and the sterilization to be repeated.

Note: Many factors can affect drying time other than sterilization wrap, such as the pack configuration that is used, sterilizer loading, cycle variations, the performance of the sterilizer, temperature and steam distribution, altitude, and ambient environmental conditions.

Post-Sterilization Cooling/Unloading

- Leave wrapped packages on the sterilizer cart until cool to avoid compromising package sterility.
- Visually inspect wrapped items as they are removed from the cart. Items that are damaged or wet should not be used.

Sterility Maintenance

- Real-time testing supports maintenance of package sterility for up to 365 days provided package integrity is maintained.
- Store wrapped packages as recommended in the ANSI/AAMI and AORN guidelines.
- Refer to and follow "Storage Prior to Use" and "Prior to Use" recommendations.

Caution: Stacking sterilized trays during storage can lead to damage of the wrap due to pressure from excess 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 healthcare facility's policy.

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