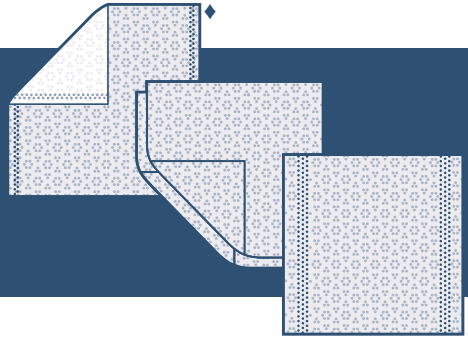




**QUICK CHECK\***  
STERILIZATION WRAP  
**SEQUENTIAL**  
STERILIZATION WRAP  
**KINGUARD ONE-STEP\***  
STERILIZATION WRAP



## Instructions for Use

### Models:

H100

H200

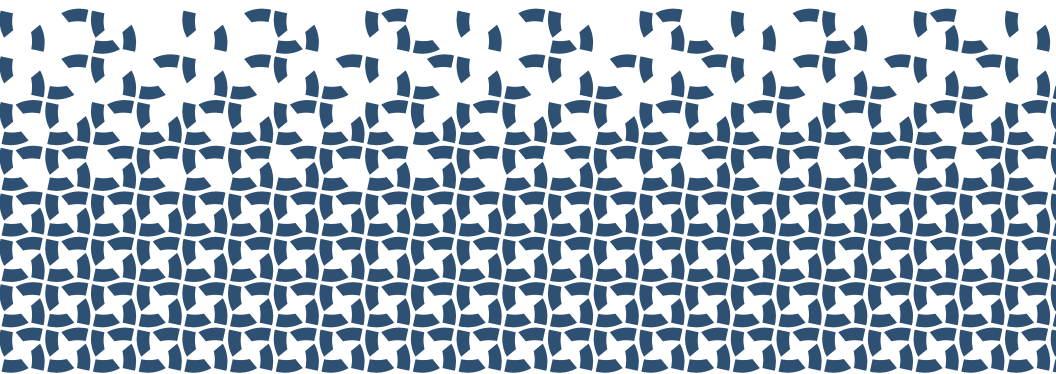
H300

H400

H500

H600

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



# Single Use Only

## Disposable

### Product Description

HALYARD\* 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. HALYARD\* QUICK CHECK\*, and KIMGUARD ONE-STEP\* Sterilization Wraps are comprised of two sheets of HALYARD\* Sequential Sterilization Wrap ultrasonically sealed 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.

HALYARD\* QUICK CHECK\*, Sequential, and KIMGUARD ONE-STEP\* Sterilization Wraps are available in various sizes (dimensions of sheet) including those offered in Table 1.

**Table 1. Dimensional Specifications of the Wraps**

Dimensions	H100	H200	H300	H400	H500	H600
9 in. x 9 in.	X <sup>1</sup>					
12 in. x 12 in.	X	X				
15 in. x 15 in.	X	X				
18 in. x 18 in.	X	X	X <sup>2</sup>	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 <sup>1</sup>	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 <sup>2</sup>	X	X	X	X	X
54 in. x 90 in.					X	

<sup>1</sup> Available in HALYARD\* Sequential Sterilization Wrap only. <sup>2</sup> Available in HALYARD\* Sequential and KIMGUARD ONE-STEP\* Sterilization Wrap only.

### Indications for Use

HALYARD\* Sterilization Wraps are intended to be used to enclose another medical device that is to be sterilized by a health care provider using:

- Pre-vacuum steam at 270°F/132°C for 4 minutes. The wrap was validated for dry times of 20 minutes for Models 100 and 200, and for 30 minutes for Models 300, 400, 500, and 600.
- 100% ethylene oxide (EO) with a concentration of 725-735 mg/L at 131°F/55°C and 40%-80% relative humidity for 60 minutes. The wrap was validated for aeration times for EO sterilization of 8 hours at 55°C or 12 hours at 43.3°C.
- Lumen, Non Lumen and Flexible Cycles in the STERIS V-PRO® 1, STERIS V-PRO® 1 Plus and STERIS V-PRO® maX Low Temperature Sterilization Systems. The wrap was validated to be effectively aerated during the pre-programmed cycles.
- Gravity steam at 250°F/121°C for 30 minutes (25 minute dry time for Models 100, 200 and 300 and 30 minute dry time for Models 400, 500 and 600)
- Advanced Sterilization Products STERRAD® Sterilization System - See Appendix - Validated Advanced Sterilization Products (ASP) Cycles
  - STERRAD® 50, 100S, and 200
  - STERRAD® NX®, [Standard Cycle, Advanced Cycle]
  - STERRAD® 100NX® [Standard Cycle, Flex Cycle, EXPRESS Cycle, DUO Cycle]

The wrap is intended to allow sterilization of the enclosed medical device(s) and also to maintain sterility of the enclosed device(s) until used.

### Warnings

- Do not use wrap in dry heat or radiation sterilization methods.

- 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 HALYARD\* 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 (refer to 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, Halyard Health recommends that the wrapped devices should be protected from contamination by an additional covering.

## Instructions for Use

The HALYARD\* QUICK CHECK\*, Sequential, and KIMGUARD ONE-STEP\* 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

## General Storage (Pre & Post Sterilization)

- Location should be clean, dust free and away from fluorescent or ultraviolet light.
- Use first in, first out (FIFO) stock rotation.
- Refer to ANSI/AAMI and AORN Guidelines for post sterilization storage conditions.

## Prior to Use

- Examine wrap and discard if damage or extraneous matter is detected.
- Thoroughly clean and dry items to be wrapped/packaged.

## Common Wrapping Techniques with HALYARD\* Family of Sterilization Wraps

- Place item(s) on wrap using typical aseptic wrapping techniques per *ANSI/AAMI ST79: Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities*. Recommendations for wrap contents are provided in Table 2.
- **If using the simultaneous wrapping technique, ensure the first fold is pulled far enough to cover all package surfaces to ensure sterility maintenance.**
- Secure the wrapped package with sterilization indicator tape or alternate closure method suitable for the sterilization method to be used.
- Closure must allow the sterilant to penetrate the wrapped package, avoid constriction of the package and maintain package integrity.

**Table 2: Wrap Model Recommendations<sup>1</sup>**

All HALYARD* Sterilization Wrap Models	Intended Load	Maximum Wrapped Package Content Weight <sup>2</sup>		
		Pre-Vacuum, Gravity and EO	STERIS V-PRO®	ASP STERRAD® 50, 100S, 200, NX and 100NX Cycles
H100	Very light weight package (e.g., towel packs, batteries)	3 lbs.	3 lbs.	10.7 lbs.
H200	Light weight package (e.g., standard linen packs, telescope with light cord)	6 lbs.	6.5 lbs.	10.7 lbs.
H300	Light to moderate weight package (e.g., general use medical instruments)	9 lbs.	9 lbs.	10.7 lbs.
H400	Moderate to heavy weight package (e.g., general use medical instruments)	13 lbs. <sup>3</sup>	10 lbs.	10.7 lbs.
H500	Heavy weight package (e.g., general use medical instruments)	17 lbs. <sup>3</sup>	10 lbs. <sup>4</sup>	10.7 lbs.
H600	Very heavy weight package (e.g., general use medical instruments)	25 lbs. <sup>3</sup>	10 lbs. <sup>4</sup>	10.7 lbs.

The following loads were used in the pre-vacuum steam and EO Sterility Maintenance Validation Studies:

- **H100:** 16 huck towels (17 in. x 29 in.)
- **H200:** 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.)
- **H300:** For pre-vac: 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 (17 in. x 29 in.), 2 fluid-resistant large drapes (76 in. x 100 in.), 1 small fluid-resistant drape (76 in. x 60 in.), 1 fluid-resistant table cover (60 in. x 90 in.)
- **H400:** 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

- **H500:** 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
- **H600:** 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

The following loads were used in the STERIS V-PRO® Sterility Maintenance Validation Studies:

- **H100:** 3 lbs. metal mass, 6 forceps
- **H200:** 2.5 lbs. metal mass, 6 forceps, V-PRO® Tray (17 in. x 10 in. x 3 ½ in.) at 4 lbs.
- **H300:** 5 lbs. metal mass, 6 forceps, V-PRO® Tray (17 in. x 10 in. x 3 ½ in.) at 4 lbs.
- **H400:** 6 lbs. metal mass, 6 forceps, V-PRO® Tray (17 in. x 10 in. x 3 ½ in.) at 4 lbs.
- **H500 and H600:** 5 lbs. metal mass, 6 forceps, V-PRO® Tray (21 in. x 10 in. x 3 ½ in.) at 5 lbs.

The following loads were used in the Gravity Steam Sterility Maintenance Validation Studies:

- **H100:** 1 tray liner (20 in. x 25 in.), 12.5 in. x 9 in. x 1 in. tray containing 1 lb. of metal mass
- **H200:** 1 tray liner (20 in. x 25 in.), 10 in. x 20 in. x 3.5 in. tray containing 3 lbs. of metal mass
- **H300:** 1 tray liner (20 in. x 25 in.), 10 in. x 20 in. x 3.5 in. tray containing 6 lbs. of metal mass
- **H400:** 1 tray liner (20 in. x 25 in.), 10 in. x 20 in. x 3.5 in. tray containing 10 lbs. of metal mass
- **H500:** 1 tray liner (20 in. x 25 in.), 11 in. x 22 in. x 3.5 in. tray containing 12 lbs. of metal mass
- **H600:** 1 tray liner (20 in. x 25 in.), 11 in. x 22 in. x 3.5 in. tray containing 20 lbs. of metal mass

The following loads were used in the ASP STERRAD® 50, 100S, 200, NX®, and 100NX® Sterility Maintenance Validation Studies:

- **H100 – H600:** APTIMAX® instrument tray (23 in. x 11 in. x 4 in.) with Tray Mat, metal and non-metal instruments

**Note:** *The loads used in each Sterility Validation Study corresponded to the maximum wrapped package content weights in Table 2.*

<sup>1</sup> 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 the most appropriate for each intended use.

<sup>2</sup> 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 (i.e., the number and size of the fluid-resistant liners or the weights of the metal mass).

<sup>3</sup> It is recommended that the user not include fluid-resistant liners in packs since this could affect the ability of the sterilant to fully penetrate and sterilize the pack contents. But note that **H400, H500, and H600** wraps have been validated for sterilant penetration with up to 3 lbs. of non-fluid resistant linen.

<sup>4</sup> The **H500** and **H600** HALYARD® QUICK CHECK® and KIMGUARD ONE-STEP® Sterilization Wraps models should be used only with the 21 in. x 10 in. V-PRO 1 tray.

## Sterilization

- HALYARD® QUICK CHECK®, Sequential, and KIMGUARD ONE-STEP® 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 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 HALYARD® QUICK CHECK®, Sequential, and KIMGUARD ONE-STEP® 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 V-PRO 1, V-PRO® 1 Plus and Flexible Cycle Low Temperature Sterilization Systems.

## Sterility Maintenance

- Real time testing supports maintenance of package sterility for at least 30 days for all grades of HALYARD® Sterilization Wrap in pre-vacuum steam, EO, and STERIS V-PRO®; however, this time-point does not prevent facilities from continuing to use established healthcare facility protocols.
- Real time testing also supports maintenance of package sterility for 1 year for HALYARD® QUICK CHECK® and KIMGUARD ONE-STEP® **H300 – H600** grades following pre-vacuum steam, EO and all cycles of STERRAD® sterilization and for 30 days following gravity steam sterilization on **H100 – H600** grades.

## 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. Halyard Health does not endorse the re-use (re-sterilization) of its sterilization wraps and does not warrant performance if product is re-used.
- Recycle, landfill or incinerate based upon state and local regulations. Recycle non-soiled wraps only.
- The wrap is composed of polypropylene plastic which has a plastics recycling code of "5."

**Appendix: Validated Advanced Sterilization Products (ASP)  
STERRAD® 50, STERRAD® 100S, STERRAD® 200, STERRAD® NX® and STERRAD® 100NX® Cycles**

**Note:** Refer to the *User's Guide* for complete instructions on load and cycle for each STERRAD® System. The instructions provided below are not intended to replace the detailed *Instructions For Use* provided with the STERRAD® Systems.

ASP STERRAD® System and Cycle	Intended Load
<p style="text-align: center;"><b>STERRAD® 50</b></p>	<p>Reusable metal and non-metal medical devices, including up to 10 lumens of the following dimensions per chamber load:</p> <ul style="list-style-type: none"> <li>• An inside diameter of 1 mm or larger and a length of 125 mm or shorter of single-channel stainless steel lumens.</li> <li>• An inside diameter of 2 mm or larger and a length of 250 mm or shorter of single-channel stainless steel lumens.</li> <li>• An inside diameter of 3 mm or larger and a length of 400 mm or shorter of single-channel stainless steel lumens.</li> <li>• An inside diameter of 6 mm or larger and a length of 310 mm or shorter of single-channel TEFLON/ Polyethylene lumens.</li> </ul> <p>Refer to the STERRAD® 50 Sterilizer User's Guide for complete instructions on load(s) and cycle(s), including chamber loading instructions (i.e., 10 lumens per load).</p>
<p style="text-align: center;"><b>STERRAD® 100S</b></p>	<p>Reusable metal and non-metal medical devices, including up to 10 lumens of the following dimensions per chamber load:</p> <ul style="list-style-type: none"> <li>• An inside diameter of 1 mm or larger and a length of 125 mm or shorter of single-channel stainless steel lumens.</li> <li>• An inside diameter of 2 mm or larger and a length of 250 mm or shorter of single-channel stainless steel lumens.</li> <li>• An inside diameter of 3 mm or larger and a length of 400 mm or shorter of single-channel stainless steel lumens.</li> <li>• An inside diameter of 6 mm or larger and a length of 310 mm or shorter of single-channel TEFLON/ Polyethylene lumens.</li> </ul> <p>Refer to the STERRAD® 100S Sterilizer User's Guide for complete instructions on load(s) and cycle(s), including chamber loading instructions (i.e., 10 lumens per load).</p>
<p style="text-align: center;"><b>STERRAD® 200</b></p>	<p>Reusable metal and non-metal medical devices, including up to 12 lumens of the following dimensions per chamber load:</p> <ul style="list-style-type: none"> <li>• An inside diameter of 1 mm or larger and a length of 125 mm or shorter of single-channel stainless steel lumens.</li> <li>• An inside diameter of 2 mm or larger and a length of 250 mm or shorter of single-channel stainless steel lumens.</li> <li>• An inside diameter of 3 mm or larger and a length of 400 mm or shorter of single-channel stainless steel lumens.</li> <li>• An inside diameter of 6 mm or larger and a length of 310 mm or shorter of single-channel TEFLON/ Polyethylene lumens.</li> </ul> <p>Refer to the STERRAD® 200 Sterilizer User's Guide for complete instructions on load(s) and cycle(s), including chamber loading instructions (i.e., 36.48 lbs.per tray load).</p>
<p style="text-align: center;"><b>STERRAD® NX® Standard Cycle</b></p>	<p>Reusable metal and non-metal medical devices, including up to 10 lumens of the following dimensions per chamber load:</p> <ul style="list-style-type: none"> <li>• An inside diameter of 1 mm or larger and a length of 150 mm or shorter of single-channel stainless steel lumens.</li> <li>• An inside diameter of 2 mm or larger and a length of 400 mm or shorter of single-channel stainless steel lumens.</li> </ul> <p>Refer to the STERRAD® NX® Sterilizer User's Guide for complete instructions on load(s) and cycle(s), including chamber loading instructions (i.e., 10.7 lbs.per load).</p>
<p style="text-align: center;"><b>STERRAD® NX® Advanced Cycle</b></p>	<p>Reusable metal and non-metal medical devices, including up to 10 lumens of the following dimensions per chamber load:</p> <ul style="list-style-type: none"> <li>• An inside diameter of 1 mm or larger and a length of 500 mm or shorter of single-channel stainless steel lumens.</li> </ul> <p>OR</p> <ul style="list-style-type: none"> <li>• One single-channel Flexible Endoscope with or without a silicone mat and no additional load. The flexible endoscope may contain:</li> <li>• A single-channel TEFLON®/Polyethylene lumen with an inside diameter of 1 mm or larger and a length of 850 mm or shorter.</li> </ul> <p>Refer to the STERRAD® NX® Sterilizer User's Guide for complete instructions on load(s) and cycle(s), including chamber loading instructions (i.e., 10.7 lbs.per load).</p>

ASP STERRAD® System and Cycle	Intended Load
<b>STERRAD® 100NX® Standard Cycle</b>	Reusable metal and non-metal medical devices, including up to 10 lumens of the following dimensions per chamber load: <ul style="list-style-type: none"> <li>An inside diameter of 0.7 mm or larger and a length of 500 mm or shorter of single-channel stainless steel lumens. (A maximum of two flexible endoscopes, one per tray per sterilization cycle.)</li> </ul> Refer to the STERRAD® 100NX® Sterilizer User's Guide for complete instructions on load(s) and cycle(s), including chamber loading instructions (i.e., 21.4 lbs.per load).
<b>STERRAD® 100NX® Flex Cycle</b>	One or two single-channel Flexible Endoscope with or without a silicone mat and no additional load. The flexible endoscope may contain: <ul style="list-style-type: none"> <li>A single-channel TEFLON®/Polyethylene lumen with an inside diameter of 1 mm or larger and a length of 850 mm or shorter. (A maximum of two flexible endoscopes, one per tray per sterilization cycle).</li> </ul> Refer to the STERRAD® 100NX® Sterilizer User's Guide for complete instructions on load(s) and cycle(s), including chamber loading instructions (i.e., 12.2 lbs.per load).
<b>STERRAD® 100NX® EXPRESS Cycle</b>	Non-lumened reusable metal and non-metal devices requiring surface sterilization, and sterilization of diffusion-restricted spaces such as the hinged portions of forceps and scissors, and rigid or semi-rigid endoscopes without lumens. <p>Refer to the STERRAD® 100NX® User's Guide for complete instructions on load(s) and cycle(s), including chamber loading instructions (i.e., 10.7 lbs.per load).</p>
<b>STERRAD® 100NX® DUO Cycle</b>	One or two single-channel Flexible Endoscope with accessory devices that are normally connected to it, with or without a silicone mat. The flexible endoscope may contain: <ul style="list-style-type: none"> <li>A single-channel TEFLON®/Polyethylene lumen with an inside diameter of 1 mm or larger and a length of 875 mm or shorter.</li> <li>Accessory devices that are normally connected to a flexible endoscope during use.</li> <li>Flexible endoscopes without lumens.</li> </ul> Refer to the STERRAD® 100NX® Sterilizer User's Guide for complete instructions on load(s) and cycle(s), including chamber loading instructions (i.e., 13.2 lbs.per load).

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15-H1-037-0-00 / 70169102