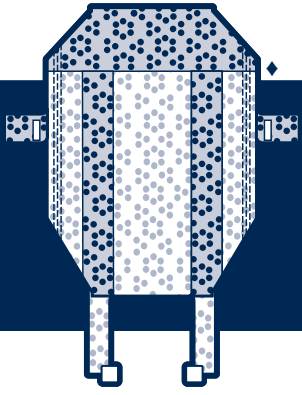
HALYARD*

SMART-FOLD* STERILIZATION WRAP



Instructions for Use

Model:
H**450**
H**650**

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

Single Use Only, Disposable

Product Description

HALYARD* SMART-FOLD* Sterilization Wrap is supplied in bulk to the customer as pre-shaped sterilization wrap which is then used to wrap a medical device or a collection of medical devices for sterilization. The SMART-FOLD* Sterilization Wrap is comprised of two pre-shaped sheets of HALYARD* Sequential Sterilization Wrap and produced by 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 white sheet has the same material composition but contains no blue pigment.

The SMART-FOLD* Sterilization Wrap features reinforcement zones, a medical device placement reference line, a white inner layer, side-tabs with closure strips and pull-tabs which allow for aseptic presentation of the sterilized medical device.

SMART-FOLD* Sterilization Wrap is available in various sizes including those offered in Table 1.

Table 1. SMART-FOLD* H450 and H650 Dimensional Specifications

Dimensions

- 22 in. x 45 in.
- 28 in. x 46 in.
- 40 in. x 47 in.
- 40 in. x 55 in.
- 48 in. x 61 in.

(Not all sizes are available in all regions.)

Indications for Use

SMART-FOLD* Sterilization Wrap is 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 a dry time of 30 minutes.
- 100% ethylene oxide (EO) with a concentration of 725-735 mg/L at 131°F/ 55ºC and 40% – 80% relative humidity for 60 minutes. The wrap was validated for aeration times for EO sterilization of 8 hours at 131°F/55°C or 12 hours at 110°F/43.3°C.
- Advanced Sterilization Products STERRAD® Sterilization System (See Appendix)
  - STERRAD® 100S
  - STERRAD® NX® [Standard Cycle, Advanced Cycle]
  - STERRAD® 100NX® [Standard, Flex, EXPRESS, and Duo 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 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 package is torn, wet, or compressed.

⚠ Precautions

- Do not open case with a sharp knife. Knives can easily cut the product.
- Prior to use, assure that all medical devices intended to be sterilized while wrapped within the SMART-FOLD* Sterilization Wrap are compatible with and sterilizable by the sterilization modality and cycle listed in the Indications for Use in these instructions. Consult the sterilization instructions for all devices intended for sterilization. Some medical devices, regardless of the sterilization method and sterilization package/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 SMART-FOLD* Sterilization Wrap should be used in accordance with the preparation 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

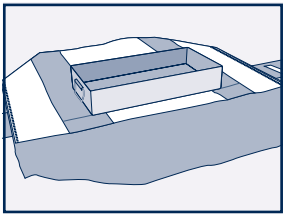
General Storage (Pre & Post Sterilization)

- 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.

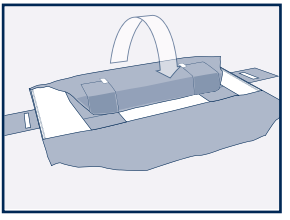
Prior to Use

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

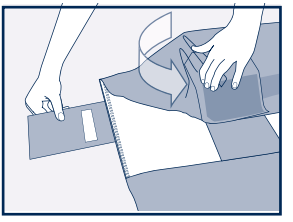
Wrapping with SMART-FOLD* Sterilization Wrap



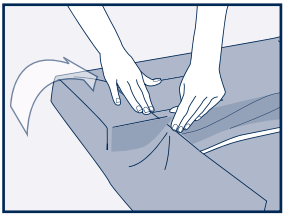
1) Position item(s) adjacent to reference line and on top of reinforcement zones.



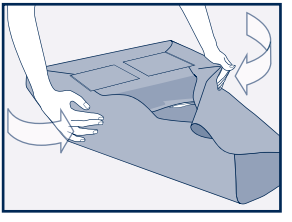
2) Fold first layer over device and cover completely.



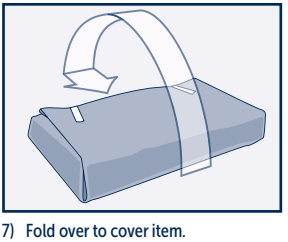
3) Gather side.



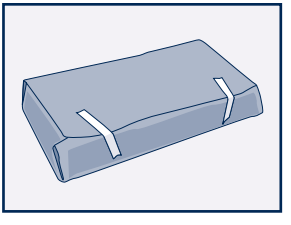
4) Fold side up and secure.
5) Repeat steps 3-5 on other side.



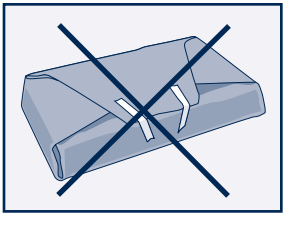
6) Gather top at both sides and fold inward.



7) Fold over to cover item.
8) Secure with a common closure (tape or alternate closure suitable for the sterilization method to be used) and label.



Front view



Incorrect final fold.

- Closure must allow the sterilant to penetrate the wrapped package, avoid constriction of the package and maintain package integrity.

Demonstrating Proper vs. Improper First Fold for SMART-FOLD* Sterilization Wrap

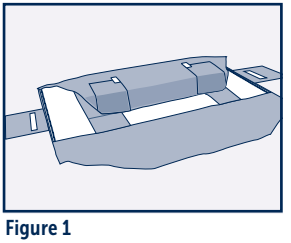


Figure 1

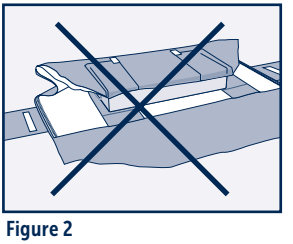


Figure 2

The correct first fold is demonstrated in **Figure 1.** Incorrect fold **Figure 2,** where the first fold is not pulled far enough to cover all package contents, is pictured in the diagram marked with an "X."

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

Table 2: Wrap Model Recommendations [1]

SMART-FOLD* Sterilization Wrap Model	Intended Loads [2]	Maximum Wrapped Package Content Weights [3]	
		Pre-vacuum and EO	ASP STERRAD® 100S, NX® and 100NX®
H450	Moderate to Heavyweight Package (for example: general use medical instruments)	13 lbs.	10.7 lbs.
H650	Moderate to Heavyweight Package (for example: general use medical instruments)	27 lbs.	10.7 lbs.

The following loads were used in Sterility Maintenance Validation Studies:

- Pre-vacuum and EO: 4 tray liners (20 in. x 25 in.) stacked in 10 in. x 10 in. tray containing 11 lbs. of metal mass
- ASP STERRAD®: Aptimax® instrument tray (23 in. x 11 in. x 4 in.) with Tray Mat, metal and non-metal instruments.

[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] Intended loads include: Medical Instruments with and without lumens that include telescopes, endoscopes, cameras, light cords, and general use medical instruments.

[3] 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 SMART-FOLD* Sterilization Wrap (i.e., the weight of the metal mass).

Sterilization

- SMART-FOLD* 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.
- See Indications for Use for dry times. **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.

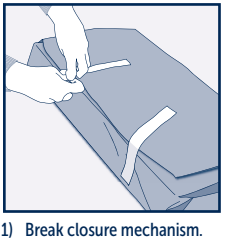
Sterility Maintenance

- Healthcare facilities may use established protocols to monitor sterility maintenance of packages wrapped with the SMART-FOLD* Sterilization Wrap in accordance with accepted standards of practice. Real-time testing simulating clinical use supports maintenance of package sterility for at least 1 year following pre-vacuum steam and EO sterilization; however, this time-point does not prevent facilities from continuing to use established healthcare facility protocols.
- Additional real time testing supports maintenance of package integrity for 1 year following STERRAD® Sterilization Systems.

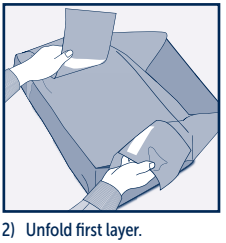
Opening

- 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.

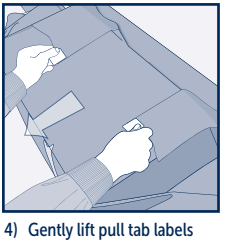
Opening a SMART-FOLD* Sterilization Wrap



1) Break closure mechanism.



2) Unfold first layer.
3) Open sides simultaneously.



4) Gently lift pull tab labels from fabric and pull towards you.

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:

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

Validated Advanced Sterilization Products (ASP)
STERRAD® 100S, STERRAD® NX® and STERRAD® 100NX® Cycles

ASP STERRAD® System and Cycle	Intended Load
STERRAD® 100S	Reusable metal and non-metal medical devices, including up to 10 lumens of the following dimensions per chamber load: • An inside diameter of 1 mm or larger and a length of 125 mm or shorter of single-channel stainless steel lumens. • An inside diameter of 2 mm or larger and a length of 250 mm or shorter of single-channel stainless steel lumens. • An inside diameter of 3 mm or larger and a length of 400 mm or shorter of single-channel stainless steel lumens. • An inside diameter of 6 mm or larger and a length of 310 mm or shorter of single-channel TEFLON®/Polyethylene lumens. 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).
STERRAD® NX® Standard Cycle	Reusable metal and non-metal medical devices, including up to 10 lumens of the following dimensions per chamber load: • An inside diameter of 1 mm or larger and a length of 150 mm or shorter of single-channel stainless steel lumens. • An inside diameter of 2 mm or larger and a length of 400 mm or shorter of single-channel stainless steel lumens. 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).
STERRAD® NX® Advanced Cycle	Reusable metal and non-metal medical devices, including up to 10 lumens of the following dimensions per chamber load: • An inside diameter of 1 mm or larger and a length of 500 mm or shorter of single-channel stainless steel lumens. OR • One single-channel Flexible Endoscope with or without a silicone mat and no additional load. The flexible endoscope may contain: • A single-channel TEFLON®/Polyethylene lumen with an inside diameter of 1 mm or larger and a length of 850 mm or shorter. 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).
STERRAD® 100NX® Standard Cycle	Reusable metal and non-metal medical devices, including up to 10 lumens of the following dimensions per chamber load: • 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.) 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).
STERRAD® 100NX® Flex Cycle	One or two single-channel Flexible Endoscope with or without a silicone mat and no additional load. The flexible endoscope may contain: • 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). 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).
STERRAD® 100NX® EXPRESS Cycle	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. 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).

ASP STERRAD® System and Cycle	Intended Load
STERRAD® 100NX® DUO Cycle	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: • A single-channel TEFLON®/Polyethylene lumen with an inside diameter of 1 mm or larger and a length of 875 mm or shorter. • Accessory devices that are normally connected to a flexible endoscope during use. • Flexible endoscopes without lumens. 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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