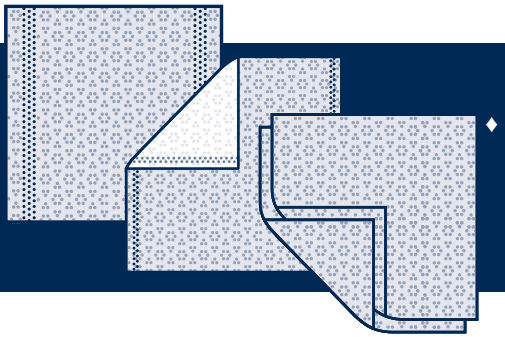
HALYARD*

ONE-STEP*, QUICK CHECK* and SEQUENTIAL STERILIZATION WRAP



Instructions for Use

Models:
H**100**
H**200**
H**300**
H**400**
H**500**
H**600**

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 HALYARD ONE-STEP* Sterilization Wraps are comprised of two sheets of HALYARD* Sequential Sterilization Wrap ultrasonically seamed on two edges. This allows for convenient wrapping with two sheets simultaneously.

Sterilization wrap is a square or rectangular sheet made of three-layer SMS (spunbond-meltblown-spunbond) polypropylene fabric treated with an antistatic treatment. The wrap allows a sterilized package to be opened aseptically.

HALYARD* 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[1]					
12 in. x 12 in.	X	X				
15 in. x 15 in.	X	X				
18 in. x 18 in.	X	X	X[2]	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[1]	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[2]	X	X	X	X	X
54 in. x 90 in.					X	

[1] Available in HALYARD* Sequential Sterilization Wrap only. [2] Available in HALYARD* Sequential and HALYARD ONE-STEP* Sterilization Wrap only. [3] For specific sizes and availability see product catalog.

Indications for Use

HALYARD* Sterilization Wraps are intended to be used to enclose another medical device that is to be sterilized by a healthcare 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.
- STERIS V-PRO® Low Temperature Sterilization Systems. The wrap was validated to be effectively aerated during the pre-programmed cycles.
    - STERIS V-PRO® 60 (Lumen, Non-Lumen and Flexible Cycles)
    - STERIS V-PRO® 1 (Lumen Cycle)
    - STERIS V-PRO® 1 Plus (Lumen and Non-Lumen Cycle)
    - STERIS V-PRO® maX (Lumen, Non-Lumen and Flexible Cycle)
- 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® NX® with ALLClear® Technology, (Standard Cycle, Advanced Cycle)
    - STERRAD® 100NX® (Standard Cycle, Flex Cycle, EXPRESS Cycle, DUO Cycle)
    - STERRAD® 100NX® with ALLClear® Technology, (Standard Cycle, Flex Cycle, EXPRESS Cycle, DUO Cycle)
- Test results validated that HALYARD ONE-STEP* Sterilization Wraps allowed sterilization of the enclosed devices by the Sterilucent™ HC 80TT Hydrogen Peroxide Sterilizer (i.e., both the Lumen and Flexible Cycles). Additionally, the HALYARD ONE-STEP* Sterilization Wrap was validated to allow effective aeration under the pre-programmed HC 80TT Sterilization Cycles. All models of the HALYARD ONE-STEP* Sterilization Wrap have been validated for use with the Sterilucent™ HC 80TT Hydrogen Peroxide Sterilizer cycles.

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, O&M Halyard recommends that the wrapped devices should be protected from contamination by an additional covering.
- Stacking heavy sterilized trays during storage can lead to damage of the wrap due to undue pressure from excess weight.

Instructions for Use

The HALYARD* 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[1]

HALYARD* Sterilization Wrap	Intended Load	Wrapped Package Content Weight[2]				
		Pre-Vacuum, Gravity and EO	STERIS V-PRO® 1, 1Plus, maX	STERIS V-PRO® 60	ASP STERRAD® 50, 100S, 200, NX®, NX® with ALLClear® Technology, 100NX® and 100NX® with ALLClear® Technology Cycles	STERILUCENT™ HC 80TT Lumen and Flex Cycles
H**100**	Very light weight package (e.g., towel packs)	3 lbs.	3 lbs.	3 lbs.	10.7 lbs.	3.4 lbs.
H**200**	Light weight package (e.g., standard linen packs, telescope with light cord)	6 lbs.	6.5 lbs.	6.5 lbs.	10.7 lbs.	6.0 lbs.
H**300**	Light to moderate weight package (e.g., general use medical instruments)	9 lbs.	9 lbs.	9 lbs.	10.7 lbs.	9.1 lbs.
H**400**	Moderate to heavy weight package (e.g., general use medical instruments)	13 lbs.[3]	10 lbs.	12 lbs.	10.7 lbs.	13.0 lbs.
H**500**	Heavy weight package (e.g., general use medical instruments)	17 lbs.[3]	10 lbs.[4]	12 lbs.	10.7 lbs.	16.1 lbs.
H**600**	Very heavy weight package (e.g., general use medical instruments)	25 lbs.[3]	10 lbs.[4]	12 lbs.	10.7 lbs.	26.0 lbs. (Lumen Cycle) 25.0 lbs. (Flexible Cycle)

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

- H**100**: 16 huck towels (17 in. x 29 in.)
- H**200**: 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.)
- H**300**: 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.)
- H**400**: 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
- H**500**: 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
- H**600**: 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:

- H**100**: 3 lbs. metal mass, 6 forceps
- H**200**: 2.5 lbs. metal mass, 6 forceps, V-PRO® Tray (17 in. x 10 in. x 3 ½ in.) at 4 lbs.
- H**300**: 5 lbs. metal mass, 6 forceps, V-PRO® Tray (17 in. x 10 in. x 3 ½ in.) at 4 lbs.
- H**400**: 6 lbs. metal mass, 6 forceps, V-PRO® Tray (17 in. x 10 in. x 3 ½ in.) at 4 lbs.
- H**500** and H**600**: 5 lbs. metal mass, 6 forceps, V-PRO® Tray (21 in. x 10 in. x 3 ½ in.) at 5 lbs.
- For V-PRO®60: Same as above, except H**400**-**600** grades validated with 8 lbs of metal mass.

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

- H**100**: 1 tray liner (20 in. x 25 in.), 12.5 in. x 9 in. x 1 in. tray containing 1 lb. of metal mass
- H**200**: 1 tray liner (20 in. x 25 in.), 10 in. x 20 in. x 3.5 in. tray containing 3 lbs. of metal mass
- H**300**: 1 tray liner (20 in. x 25 in.), 10 in. x 20 in. x 3.5 in. tray containing 6 lbs. of metal mass
- H**400**: 1 tray liner (20 in. x 25 in.), 10 in. x 20 in. x 3.5 in. tray containing 10 lbs. of metal mass
- H**500**: 1 tray liner (20 in. x 25 in.), 11 in. x 22 in. x 3.5 in. tray containing 12 lbs. of metal mass
- H**600**: 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:

- H**100** – H**600**: APTIMAX® instrument tray (23 in. x 11 in. x 4 in.) with Tray Mat, metal and non-metal instruments

Test results validated that HALYARD ONE-STEP* Sterilization Wraps allowed sterilization of the enclosed devices by the Sterilucent™ HC 80TT Hydrogen Peroxide Sterilizer (i.e., both the Lumen and Flexible Cycles). Additionally, the HALYARD ONE-STEP* Sterilization Wrap was validated to allow effective aeration under the pre-programmed HC 80TT Sterilization Cycles. All models of the HALYARD ONE-STEP* Sterilization Wrap have been validated for use with the Sterilucent™ HC 80TT Hydrogen Peroxide Sterilizer cycles.

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

[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 the 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 (i.e., the number and size of the fluid-resistant linens or the weights of the metal mass).

[3] It is recommended that the user not include fluid-resistant linens in packs since this could affect the ability of the sterilant to fully penetrate and sterilize the pack contents. But note that H**400**, H**500**, and H**600** wraps have been validated for sterilant penetration with up to 3 lbs. of non-fluid resistant linen.

[4] The H**500** and H**600** HALYARD* QUICK CHECK* and HALYARD ONE-STEP* Sterilization Wraps models should be used only with the 21 in. x 10 in. V-PRO 1 tray.

Sterilization

- HALYARD* 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.
- Packages are ready for immediate unloading if sterilized in the V-PRO® 60, V-PRO® 1, V-PRO® 1 Plus, and maX Flexible Cycle Low Temperature Sterilization Systems.

Sterility Maintenance

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.
Per ANSI/AAMI ST79, Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities, the shelf life of facility-sterilized items is event-related and should be based on the quality of the packaging material, the storage conditions, the methods and conditions of transport, and the amount and conditions of handling. Inventory should be rotated on a "first in, first out" basis. The facility policy should be based on the guidance provided in ANSI/AAMI ST 79, 11.1.3.

Note: *The loss of sterility is regarded as event-related rather than time-related. For additional information, see ISO/TS 16775, ANSI/AAMI ST65, and Reference [21] in ISO 11607.*

In accordance with industry standards and FDA's guidance, O&M Halyard has performed a battery of validation testing, including sterilization efficacy, bioaerosol and package maintenance integrity and has received FDA 510K clearance for HALYARD* Sterilization Wrap used in the sterilization modalities listed in Table 3.

Table 3: Summary of Approved Sterilization Modalities and Packaging Integrity Testing

	Steam Sterilization		Low Temperature Sterilization			
Time Point	**Pre-vac**	**Gravity**	**[1]V-PRO®**	**[2] STERRAD®**	**EO**	**[3]Sterilucent™**
1-Year	X		X	X	X	
6-Months						X
30-Days		X				

[1] STERIS V-PRO® Low Temperature Sterilization Systems

- STERIS® V-PRO® 60 (Lumen, Non-Lumen and Flexible Cycles)
- STERIS® V-PRO® 1 (Lumen Cycle)
- STERIS® V-PRO® 1 Plus (Lumen and Non-Lumen Cycle)
- STERIS® V-PRO® maX (Lumen, Non-Lumen and Flexible Cycle)

[2] Advanced Sterilization Products (ASP) STERRAD® Sterilization System Cycles, STERRAD® 50, 100S, and 200

- STERRAD® 50, 100S, and 200
- STERRAD® NX®, (Standard Cycle, Advanced Cycle)
- STERRAD® 100NX® (Standard Cycle, Flex Cycle, EXPRESS Cycle, DUO Cycle)
- STERRAD® NX® with ALLClear® Technology, (Standard Cycle, Advanced Cycle)
- STERRAD® 100NX® with ALLClear® Technology (Standard Cycle, Flex Cycle, EXPRESS Cycle, DUO Cycle)

[3] Sterilucent™ HC 80TT

- HC 80TT with Cycle Guardian™ (Lumen and Flexible Cycle)

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. O&M HALYARD 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® 50, STERRAD® 100S, STERRAD® 200, STERRAD® NX®, STERRAD® NX® with ALLClear® Technology, STERRAD® 100NX® and STERRAD® 100NX® with ALLClear® Technology Cycles

ASP STERRAD® System and Cycle	Intended Load
STERRAD® 50	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® 50 Sterilizer User's Guide for complete instructions on load(s) and cycle(s), including chamber loading instructions (i.e., 10 lumens per 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® 200	Reusable metal and non-metal medical devices, including up to 12 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® 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).

ASP STERRAD® System and Cycle	Intended Load
STERRAD® NX® Standard Cycle **STERRAD® NX® with ALLClear® Technology 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 and STERRAD® NX® with ALLClear® Technology Sterilizers 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 **STERRAD® NX® with ALLClear® Technology 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 and STERRAD® NX® with ALLClear® Technology Sterilizers 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 **STERRAD® 100NX® with ALLClear® Technology 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 and STERRAD® 100NX® with ALLClear® Technology Sterilizers 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 **STERRAD® 100NX® with ALLClear® Technology 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 and STERRAD® 100NX® with ALLClear® Technology Sterilizers 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 **STERRAD® 100NX® with ALLClear® Technology 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 and STERRAD® 100NX® with ALLClear® Technology Sterilizers 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® DUO Cycle **STERRAD® 100NX®with ALLClear® Technology 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 and STERRAD® 100NX® with ALLClear® Technology Sterilizers User's Guide for complete instructions on load(s) and cycle(s), including chamber loading instructions (i.e., 13.2 lbs.per load).

Validated STERIS® V-PRO® 60 Cycles

STERIS® System and Cycle	Intended Load

STERIS® V-PRO® 60 Lumen Cycle	Reusable metal and non-metal medical devices including instruments with diffusion-restricted spaces (such as the hinged portion of forceps or scissors) and single, dual or triple channeled rigid/semi-rigid endoscopes, with the following configurations:
	• Single or dual channeled devices with stainless steel lumens with
	  • An inside diameter of 0.77 mm or larger and a length of 410 mm or shorter
	• Triple channeled devices with stainless steel lumens with
	  • An inside diameter of 1.2 mm or larger and a length of 257 mm or shorter
	  • An inside diameter of 1.8 mm or larger and a length of 310 mm or shorter or
	  • An inside diameter of 2.8 mm or larger and a length of 317 mm or shorter

STERIS® V-PRO® 60 Flexible Cycle	Single or dual channeled Flexible Surgical Endoscopes or Bronchoscopes with lumens that have: • An inside diameter of 1 mm or larger and a length of 990 mm or shorter.
STERIS® V-PRO® 60 Non-Lumen Cycle	Reusable metal and non-metal non-lumened medical devices including non-lumened rigid, semi-rigid and flexible endoscopes and medical devices with stainless steel or titanium diffusion-restricted spaces such as the hinged portion of forceps or scissors.

Validated Sterilucent™ HC80TT Hydrogen Peroxide Sterilizer Cycles

Sterilucent™ HC 80TT Cycles	Intended Load
Lumen Cycle	Reusable metal and non-metal devices including devices with diffusion-restricted spaces such as the hinged portion of forceps and scissors and up to fifteen (15) stainless steel lumens per load with the following dimensions: Single or dual channeled rigid and semi-rigid endoscopes, with stainless steel lumens that are: • ≥ 0.77 mm internal diameter (ID) and ≤ 410 mm long, or • ≥1.33 mm ID and ≤ 430 mm long; and, Triple channeled rigid and semi-rigid endoscopes, with stainless steel lumens that are: • ≥ 1.00 mm ID and ≤ 310 mm long (Refer to the HC 80TT User Manual for complete instructions on load(s) and cycle(s), including chamber loading instructions.)
Flexible Cycle	Reusable rigid or semi-rigid non-lumen medical devices including non-lumen devices with metallic diffusion-restricted spaces such or mated surfaces such as the hinged portion of forceps or scissors; Single channel flexible endoscopes with flexible lumens that are: • ≥ 1.00 mm internal diameter (ID) and ≤ 1280 mm long, and, Dual Channel flexible endoscopes with flexible lumens that are: • ≥ 0.80 mm ID and ≤ 1000 mm long (Refer to the HC 80TT User Manual for complete instructions on load(s) and cycle(s), including chamber loading instructions.)

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