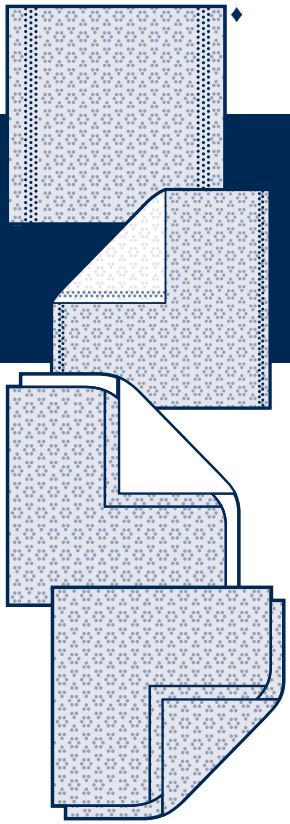
HALYARD*

ONE-STEP*, QUICK CHECK*, QUICK CHECK INTERLEAVED* and SEQUENTIAL STERILISATION 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 outside of the United States.

§ Availability may vary according to the geography.

Single Use Only
Disposable
Product Description

HALYARD* Sterilisation 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 sterilisation. HALYARD* QUICK CHECK*, and HALYARD ONE-STEP* Sterilisation Wraps are comprised of two sheets of HALYARD* Sequential Sterilisation Wrap ultrasonically seamed on two edges. This allows for convenient wrapping with two sheets simultaneously.

The sheets of sterilisation 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 white sheet has the same material composition but contains no blue pigment. The wrap allows a sterilized package to be opened aseptically.

HALYARD* Sterilisation 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
22.86 cm x 22.86 cm	x[1]					
30.48 cm x 30.48 cm	x	x				
38.1 cm x 38.1 cm	x	x				
45.72 cm x 45.72 cm	x	x	x[2]	x	x	
50.8 cm x 50.8 cm	x					
60.96 cm x 60.96 cm	x	x	x	x	x	
76.2 cm x 76.2 cm	x	x	x	x[1]	x	
91.44 cm x 91.44 cm	x	x	x	x	x	x
101.6 cm x 101.6 cm	x	x	x	x		x
114.3 cm x 114.3 cm	x		x	x	x	x
121.92 cm x 121.92 cm	x	x	x	x	x	x
137.16 cm x 137.16 cm	x	x	x	x	x	x
152.4 cm x 152.4 cm					x	
137.16 cm x 182.88 cm	x[2]	x	x	x	x	x
137.16 cm x 228.6 cm					x	

[1] Available in HALYARD* Sequential Sterilisation Wrap only. [2] Available in HALYARD* Sequential and HALYARD ONE-STEP* Sterilisation Wrap only.

Indications for Use

HALYARD* Sterilisation Wraps are intended to be used to enclose another medical device that is to be sterilised by a healthcare provider using:

- Pre-vacuum steam at 132°C /270°F 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 55°C/131°F and 40%-80% relative humidity for 60 minutes. The wrap was validated for aeration times for EO Sterilisation of 8 hours at 55°C or 12 hours at 43.3°C.
- STERIS® V-PRO® Low Temperature Sterilisation 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 121°C /250°F 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 Sterilisation Products STERRAD® Sterilisation System - See Appendix - Validated Advanced Sterilisation 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)
- STERILUCENT® PSD-85 Hydrogen Peroxide Steriliser Lumen and Non Lumen Cycles. The wrap was validated to allow effective aeration under the pre-programmed PSD-85 Sterilisation Cycles.

The wrap is intended to allow sterilisation 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 sterilisation 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.
- Do not reuse. This wrap is single use only.
- Halyard does not endorse the reuse (resterilisation) of its sterilisation wraps, as product performance and degradation limits following reuse have not been established or validated.

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 sterilised while wrapped within the HALYARD* Sterilisation Wraps are compatible with and sterilisable by the sterilisation modality and cycle listed in the Indications for Use in these directions. Consult the sterilisation instructions for all devices intended for sterilisation. Some medical devices, regardless of the sterilisation method and sterilisation wrap/container used, may require special consideration in packing configurations to ensure sterilisation (refer to EN ISO TS 16775 Packaging for terminally sterilised medical devices – Guidance on the application of ISO 11607-1 and ISO 11607-2 and/or local guidelines).
- Do not use in the presence of flammable anesthesia. The wrap is non-conductive.
- If sterilisation 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* Sterilisation Wraps should be used in accordance with the preparation, wrapping, and sterilisation chamber loading recommendations of the following standards:

- BS EN ISO 11607-1:2020 Packaging for terminally sterilized medical devices. Requirements for materials, sterile barrier systems and packaging systems.
- EN 868-2: 2017 Packaging for terminally sterilised medical devices, Sterilisation wrap, Requirements and test methods.
- BS EN ISO 11607-2:2020 Packaging for terminally sterilized medical devices. Validation requirements for forming, sealing and assembly processes.
- EN ISO TS 16775 Packaging for terminally sterilized medical devices – Guidance on the application of ISO 11607-1 and ISO 11607-2
- BS EN ISO 10993-7:2008 Biological evaluation of medical devices. Ethylene oxide sterilization residuals.
- EN 13060:2014 Small steam sterilisers.
- BS EN 285:2015 Sterilization. Steam sterilizers. Large sterilizers.
- EN 1422: 2014 Sterilisers for medical purposes, Ethylene oxide sterilisers, Requirements and test methods.

General Storage (Pre & Post Sterilisation)

- Location should be clean, dust free and away from fluorescent or ultraviolet light.
- Use first in, first out (FIFO) stock rotation.
- Refer to EN ISO 11607 Packaging for terminally sterilized medical devices and/or local guidelines.

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 Sterilisation Wraps

- Place item(s) on wrap using typical aseptic wrapping techniques as per EN ISO TS 16775 Packaging for terminally sterilized medical devices – Guidance on the application of ISO 11607-1 and ISO 11607-2. 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 sterilisation indicator tape or alternate closure method suitable for the sterilisation 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* Sterilisation Wrap	Intended Load	Maximum 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® Lumen and Non-Lumen Cycles	STERILUCENT® HC 80TT Lumen and Flexible Cycles
H**100**	Very light weight package (e.g., towel packs)	1.36 kg	1.36 kg	1.36 kg	4.85 kg	1.36 kg	1.54 kg
H**200**	Light weight package (e.g., standard linen packs, telescope with light cord)	2.72 kg	2.95 kg	2.95 kg	4.85 kg	1.36 kg	2.72 kg
H**300**	Light to moderate weight package (e.g., general use medical instruments)	4.08 kg	4.08 kg	4.08 kg	4.85 kg	1.36 kg	4.13 kg
H**400**	Moderate to heavy weight package (e.g., general use medical instruments)	5.90 kg [3]	4.54 kg	5.44 kg	4.85 kg	4.08 kg	5.90 kg
H**500**	Heavy weight package (e.g., general use medical instruments)	7.71 kg[3]	4.54 kg[4]	5.44 kg	4.85 kg	4.08 kg	7.30 kg
H**600**	Very heavy weight package (e.g., general use medical instruments)	11.34 kg[3]	4.54 kg[4]	5.44 kg	4.85 kg	4.54 kg (Lumen Cycle) 11.34 kg (Non-Lumen Cycle)	11.79 kg (Lumen Cycle) 11.34 kg (Flexible Cycle)

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

- H**100**: 16 huck towels (43.18 cm x 73.66 cm)
- H**200**: 2 huck towels (43.18 cm x 73.66 cm), 2 fluid-resistant U-drapes (172.72 cm x 276.86 cm), 1 fluid-resistant universal bar drape (177.8 cm x 274.32)
- H**300**: For pre-vac: 15 huck towels (43.18 cm x 73.66 cm), 1 small fluid-resistant drape (152.4 cm x 193.04 cm), 2.27 kg of metal mass. For EO: 16 huck towels (43.18 cm x 73.66 cm), 2 fluid-resistant large drapes (193.04 cm x 254 c m), 1 small fluid-resistant drape (193.04 cm x 152.4 cm), 1 fluid-resistant table cover (152.4 cm x 228.6 cm)
- H**400**: 4 tray liners (50.8 cm x 63.5 cm) stacked, 25.4 cm x 25.4 cm x 8.89 cm tray containing 4.99 kg of metal mass
- H**500**: 4 tray liners (50.8 cm x 63.5 cm) stacked, 25.4 cm x 25.4 cm x 8.89 cm tray containing 6.0 kg of metal mass
- H**600**: 4 tray liners (50.8 cm x 63.5 cm) stacked, 25.4 cm x 25.4 cm x 8.89 cm tray containing 10.43 kg of metal mass

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

- H**100**: 1.36 kg metal mass, 6 forceps
- H**200**: 1.13 kg metal mass, 6 forceps, V-PRO® Tray (43.18 cm x 25.4 cm x 8.89 cm) at 1.81 kg
- H**300**: 2.27 kg metal mass, 6 forceps, V-PRO® Tray. (43.18 cm x 25.4 cm x 8.89 cm) at 1.81 kg
- H**400**: 2.72 kg metal mass, 6 forceps, V-PRO® Tray (43.18 cm x 25.4 cm x 8.89 cm) at 1.81 kg
- H**500** and H**600**: 2.27 kg metal mass, 6 forceps, V-PRO® Tray. (53.34 cm x 25.4 cm x 8.89 cm) at 2.27 kg
- For V-PRO®60: Same as above, except H**400**-**600** grades validated with 3.37 kg of metal mass

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

- H**100**: 1 tray liner (50.8 cm x 63.5 cm), 31.75 cm x 22.86 cm x 2.54 cm tray containing 0.454 kg of metal mass
- H**200**: 1 tray liner (50.8 cm x 63.5 cm), 25.4 cm x 50.8 cm x 8.89 cm tray containing 1.36 kg of metal mass
- H**300**: 1 tray liner (50.8 cm x 63.5 cm), 25.4 cm x 50.8 cm x 8.89 cm tray containing 2.72 kg of metal mass
- H**400**: 1 tray liner (50.8 cm x 63.5 cm), 25.4 cm x 50.8 cm x 8.89 cm tray containing 4.54 kg of metal mass
- H**500**: 1 tray liner (50.8 cm x 63.5 cm), 27.94 cm x 55.88 cm x 8.89 cm tray containing 5.44 kg of metal mass
- H**600**: 1 tray liner (50.8 cm x 63.5 cm), 27.94 cm x 55.88 cm x 8.89 cm tray containing 9.07 kg of metal mass

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

- H**100** – H**600**: APTIMAX® instrument tray (58.42 cm x 27.94 cm x 10.16 cm) with Tray Mat, metal and non-metal instruments

The following loads were used in the STERILUCENT® PSD-85 Sterility Maintenance Validation Studies:

- Stainless Steel Tray (SU2987), Silicone Mat (SL197), Stainless Steel Dunnage to make final total weight tested above.

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 1.36 kg of non-fluid resistant linen.

[4] The H**500** and H**600** HALYARD* QUICK CHECK* and HALYARD ONE-STEP* Sterilisation Wraps models should be used only with the 53.34 cm x 25.4 cm V-PRO 1 tray.

Sterilisation

- HALYARD* Sterilisation Wraps are intended for use with the common healthcare sterilisation parameters listed in the Indications for Use. The steriliser manufacturer should be consulted for appropriate steriliser loading configurations.
- If a steriliser malfunctions or a cycle is aborted before completion, packages should be re-wrapped prior to being placed into another sterilisation 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 sterilisation wrap, including but not limited to: the pack configuration that is used, cycle variations, the performance of the steriliser machine, temperature distribution, steam generation, altitude, and ambient temperature and humidity.* Sterilisers vary widely in design and performance characteristics. The user should consult the steriliser manufacturer's operator manual for specific drying times.

Post-Sterilisation Cooling/Unloading

- Leave wrapped packages on the steriliser 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 sterilised in the V-PRO® 60, V-PRO® 1, V-PRO® 1 Plus, and maX Low Temperature Sterilisation 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 BS EN ISO 11607-1:2020, Section 8 Packaging system performance and stability under
  8.1 General
  Sterile Barrier System Integrity Testing (used to establish the capability of the sterile barrier system to maintain sterility) shall be performed after packaging system performance testing and stability testing on sterilised samples.

  Sterile barrier system integrity testing may be performed by testing the integrity of the materials and the integrity of the seals and closures separately.

  Note 1: *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].*
- Per ANSI/AAMI ST79:2017, 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 79:2017, 11.1.3.
- In accordance with industry standards, O&M Halyard has performed a battery of validation testing, including sterilization efficacy, bioaerosol and package maintenance integrity for HALYARD* Sterilization Wrap used in the sterilization modalities listed in the table below.

Summary of Approved Sterilization Modalities and Packaging Integrity Testing

	Steam Sterilization		Low Temperature Sterilization			
Time Point	**Pre-vac**	**Gravity**	**V-PRO®[1]**	**STERRAD®[2]**	**EO**	**STERILUCENT™[3]**
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)
- STERIS® V-PRO® maX2 (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® ALLClear 50, 100S, and 200
- STERRAD® NX® ALLClear®, (Standard Cycle, Advanced Cycle)

[3] Sterilucent™, PSD-85 and HC 80TT

- PSD-85 (Lumen and Non-Lumen)
- 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.
- 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."

Note: *Any serious incident that has occurred in relation to the device should be reported to O&M Halyard at PIQ@hyh.com and the competent authority of the Member State in which the user is established.*

Appendix:

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

Validated Advanced Sterilisation Products (ASP)
STERRAD® 50, STERRAD® 100S, STERRAD® 200, STERRAD® NX, STERRAD® NX® with ALLClear® Technology, STERRAD® 100NX® Cycles, and STERRAD® 100NX® Cycles with ALLClear® Technology

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 Steriliser 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 Steriliser 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 Steriliser User's Guide for complete instructions on load(s) and cycle(s), including chamber loading instructions (i.e., 16.55 kg per tray load).
STERRAD® NX® Standard Cycle **STERRAD NX® Systems 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® Steriliser User's Guide and STERRAD® NX® with ALLClear® Technology Steriliser User's Guide for complete instructions on load(s) and cycle(s), including chamber loading instructions (i.e., 4.85 kg per load).
STERRAD® NX® Advanced Cycle **STERRAD NX® Systems 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® Steriliser User's Guide and STERRAD® NX® with ALLClear® Technology Steriliser User's Guide for complete instructions on load(s) and cycle(s), including chamber loading instructions (i.e., 4.85 kg per load).

ASP STERRAD® System and Cycle	Intended Load
STERRAD® 100NX® Standard Cycle **STERRAD 100NX® Systems 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 sterilisation cycle) Refer to the STERRAD® 100NX® Steriliser User's Guide and STERRAD® 100NX® with ALLClear® Technology Steriliser User's Guide for complete instructions on load(s) and cycle(s), including chamber loading instructions (i.e., 9.71 kg per load).
STERRAD® 100NX® Flex Cycle **STERRAD 100NX® Systems 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 sterilisation cycle) Refer to the STERRAD® 100NX® Steriliser User's Guide and STERRAD® 100NX® with ALLClear® Technology Steriliser User's Guide for complete instructions on load(s) and cycle(s), including chamber loading instructions (i.e., 5.53 kg per load).
STERRAD® 100NX® EXPRESS Cycle **STERRAD 100NX® Systems with ALLClear® Technology EXPRESS Cycle**	Non-lumened reusable metal and non-metal devices requiring surface sterilisation, and sterilisation 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., 4.85 kg per load). Refer to the STERRAD® 100NX® User's Guide and STERRAD® 100NX® with ALLClear® Technology Steriliser User's Guide for complete instructions on load(s) and cycle(s), including chamber loading instructions (i.e., 4.85 kg per load).
STERRAD® 100NX® DUO Cycle **STERRAD 100NX® Systems 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® Steriliser User's Guide and STERRAD® 100NX® with ALLClear® Technology Steriliser User's Guide for complete instructions on load(s) and cycle(s), including chamber loading instructions (i.e., 5.99 kg per load).

Validated STERIS® V-PRO® 60 Cycles

STERIS® System and Cycle	Intended Load
STERIS® V-PRO® 60, V-PRO® 1, V-PRO® 1 Plus, V-PRO® maX Lumen Cycle	**V-PRO® 60** 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 275 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 **V-PRO® 1 and V-PRO® 1 Plus** Instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors. Medical devices with a single lumen with: • an inside diameter of 1 mm or larger and a length of 125 mm or shorter • an inside diameter of 2 mm or larger and a length of 250 mm or shorter • an inside diameter of 3 mm or larger and a length of 400 mm or shorter **V-PRO® maXCycle** Instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors Medical devices, including rigid endoscopes, with a single stainless steel lumen with: • an inside diameter of 1 mm or larger and a length of 125 mm or shorter • an inside diameter of 2 mm or larger and a length of 250 mm or shorter • an inside diameter of 3 mm or larger and a length of 400 mm or shorter
STERIS® V-PRO® 60, V-PRO® maX Flexible Cycle	**V-PRO® 60 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. **V-PRO® maX Cycle** Instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors Medical devices, including rigid endoscopes, with a single stainless steel lumen with: • an inside diameter of 1 mm or larger and a length of 125 mm or shorter • an inside diameter of 2 mm or larger and a length of 250 mm or shorter • an inside diameter of 3 mm or larger and a length of 400 mm or shorter
STERIS® System and Cycle	Intended Load
STERIS® V-PRO® 60, V-PRO® 1 Plus, V-PRO® maX 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® PSD-85 Hydrogen Peroxide Steriliser Cycles

STERILUCENT® PSD-85 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 10 single channel stainless steel lumened devices of the following dimensions per chamber load: • An inside diameter of 1 mm or larger and a length of 60 mm or shorter • An inside diameter of 2 mm or larger and a length of 250 mm or shorter • An inside diameter of 3 mm or larger and a length of 350 mm or shorter (Refer to the PSD-85 User Manual for complete instructions on load(s) and cycle(s), including chamber loading instructions (i.e. 4.54 kg per load))
Non-Lumen Cycle	Non-lumened reusable metal and non-metal devices including devices with stainless steel diffusion-restricted spaces such as the hinged portion of forceps and scissors. (Refer to the PSD-85 User Manual for complete instructions on load(s) and cycle(s), including chamber loading instructions (i.e. 11.34 kg per load)).

Validated STERILUCENT® HC80TT Hydrogen Peroxide Steriliser Cycles

STERILUCENT® HC 80T Cycles	Intended Load
Lumen Cycle	Reusable metal and nonmetal 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 (i.e. 9.1 kg per load).
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 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 (i.e. 11.3 kg per load).

HALYARD ONE-STEP* Sterilisation Wraps are intended to enclose another medical device that is to be sterilized by a healthcare provider using the STERILUCENT® HC 80TT Hydrogen Peroxide Steriliser that includes a Lumen Cycle and Flexible Cycle.

Test results validated that HALYARD ONE-STEP* Sterilisation Wraps allowed sterilisation of the enclosed devices by the STERILUCENT® HC 80TT Hydrogen Peroxide Steriliser (i.e., both the Lumen and Flexible Cycles). Additionally, the HALYARD ONE-STEP* Sterilisation Wrap was validated to allow effective aeration under the pre-programmed HC 80TT Sterilisation Cycles. All models of the HALYARD ONE-STEP* Sterilisation Wrap have been validated for use with the STERILUCENT® HC 80TT Hydrogen Peroxide Steriliser cycles as described below:

Lumen Cycle:

Reusable metal and nonmetal 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 (i.e. 9.1 kg per load).

Flexible Cycle:

Reusable rigid or semi-rigid non-lumen medical devices including non-lumen devices with metallic diffusion-restricted spaces or mated surfaces such as the hinged portion of forceps or scissors;

Single channel flexible endoscopes with flexible lumens that are:

- ≥ 1.00 mm 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 (i.e. 11.3 kg per load).

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