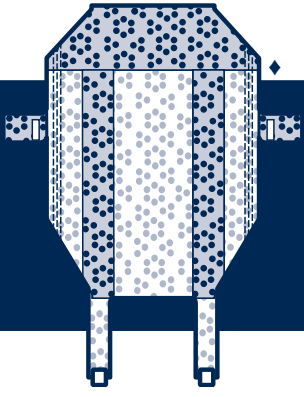
HALYARD*

SMART-FOLD* STERILIZATION WRAP



Instructions for Use

Model:
H450
H650

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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. Each sheet is composed of a three-layer SMS (spunbond-meltblown-spunbond) polypropylene fabric treated with an antistatic treatment.

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. The white sheet has the same material composition but contains no blue pigment.

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	H450	H650
22 in. x 45 in.	x	x
28 in. x 46 in.	x	x
40 in. x 47 in.	x	x
40 in. x 55 in.	x	x
48 in. x 61 in.	x	x

(All grades may not be 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/ 55°C 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]
- 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)
    - STERIS® V-PRO® maX 2 (Lumen, Non-Lumen and Flexible 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 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.
- Stacking heavy sterilized trays during storage can lead to damage of the wrap due to undue pressure from the excess weight.

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

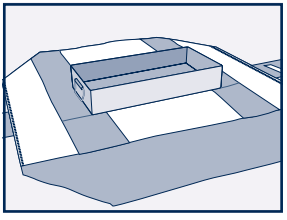
General Storage (Pre & Post Sterilization)

- 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.

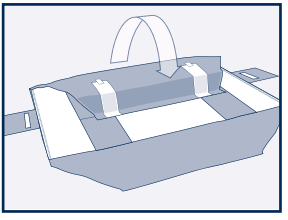
Prior to Use

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

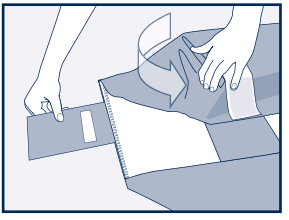
Wrapping with SMART-FOLD* Sterilization Wrap



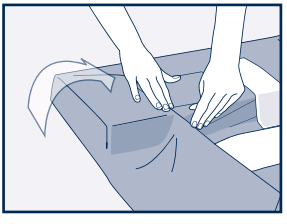
1) Position item(s) adjacent to reference line and on top of reinforcement zones.



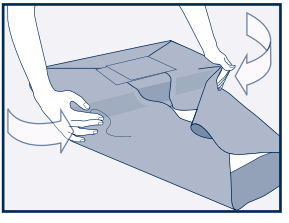
2) Fold first layer over device and cover completely.



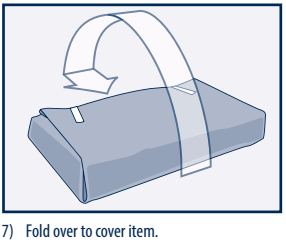
3) Gather side.



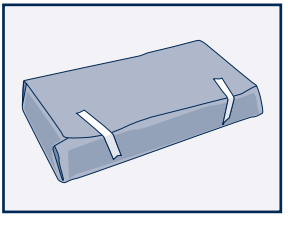
4) Fold side up and secure.
5) Repeat steps 3-5 on other side.



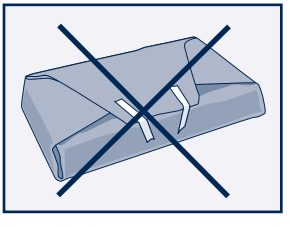
6) Gather top at both sides and fold inward.



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.

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

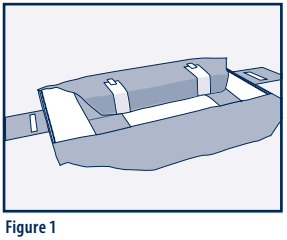


Figure 1

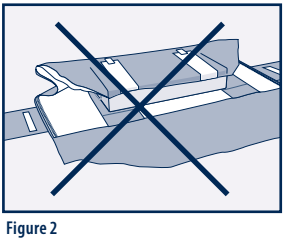


Figure 2

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.

SMART-FOLD* Sterilization Wrap Model	Intended Loads [2]	Maximum Wrapped Package Content Weights [3]	
		Pre-vacuum and EO	ASP STERRAD® 100S, NX and 100NX
H650	Moderate to Heavyweight Package (for example: general use medical instruments)	25 lbs.	10.7 lbs.

SMART-FOLD* Sterilization Wrap Model	Intended Loads[2]	Maximum Wrapped Package Content Weights[3]						
		STERIS® V-PRO® 1 V-PRO® 1 Plus V-PRO® maX V-PRO® maX 2 Lumen	STERIS® V-PRO® 1 Plus V-PRO® maX V-PRO® maX 2 Non-Lumen	STERIS® V-PRO® maX V-PRO® maX 2 Flexible	STERIS® V-PRO® 60 Lumen	STERIS® V-PRO® 60 Non-Lumen	STERIS® V-PRO® 60 Flexible	STERIS® V-PRO® maX 2 Fast Non-Lumen[4]
H450	Moderate to Heavyweight Package (for example: general use medical instruments)	13 lbs.	13 lbs.	13 lbs.	11 lbs.	12 lbs.	The validation studies were conducted with one flexible endoscope packaged into a tray with silicone wrap, and instrument organizers and light cord (if not integral to scope) and no additional load.	N/A
H650	Moderate to Heavyweight Package (for example: general use medical instruments)	19.65 lbs.	25 lbs.– maX 2, 19.65 – maX, 1 and 1 plus	24 lbs.	11 lbs.	12 lbs.		N/A

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.
- STERIS®: V-PRO® Tray (10 in. x 21 in.), 6 surgical forceps, 1 SCBI (self-contained biological indicators), metal mass to reach total weight.

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

[4] The Fast Non-Lumen cycle is intended to sterilize pouched instrument trays only and is therefore not intended to be used for sterilization of HALYARD* SMART-FOLD* Sterilization Wraps.

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.
- Packages are ready for immediate unloading if sterilized in the V-PRO® 60, V-PRO® 1, V-PRO® 1 Plus, V-PRO® maX, and V-PRO® maX 2 and maX Low Temperature Sterilization Systems.

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 30 days following pre-vacuum steam and EO sterilization.

- Additional real time testing supports maintenance of package integrity for 1 year following STERRAD® Sterilization Systems.
- For 1 year following STERIS® V-PRO® 60, STERIS® V-PRO® maX, STERIS® V-PRO® maX 2, STERIS® V-PRO® 1 and V-PRO® 1 Plus.
- These time-points do not prevent facilities from continuing to use established healthcare facility protocols. The facility policy should be based on the guidance provided in ANSI/AAMI ST79:2017, 11.1.3 which is shown below.

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.

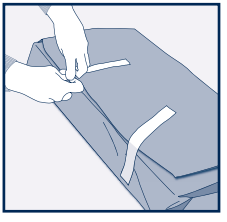
Per ANSI/AAMI ST79:2017, Comprehensive guide to steam sterilization and sterility assurance in health care facilities, (ANSI/AAMI ST79:2017, 11.1.3)

The health care facility should establish policies and procedures for determining shelf life. 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. (See the standard for further guidance.)

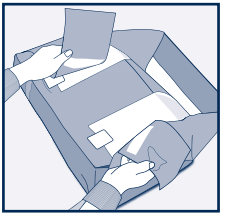
Opening

- 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.

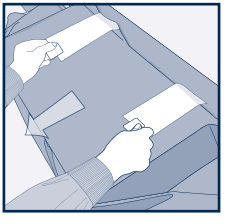
Opening a SMART-FOLD* Sterilization Wrap



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).

ASP STERRAD® System and Cycle	Intended 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).
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).

Validated STERIS® V-PRO® Cycles

Validated Low Temperature Sterilization Products STERIS® V-PRO® 1, STERIS® V-PRO® 1 Plus, STERIS® V-PRO® maX, STERIS® V-PRO® maX 2, and STERIS® V-PRO® 60, Lumen[5] Cycles

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

STERIS® V-PRO® System Lumen Cycle	Intended Load

STERIS® V-PRO® 1
STERIS® V-PRO® 1 Plus
STERIS® V-PRO® maX
STERIS® V-PRO® maX 2
	STERIS® V-PRO® 1 and STERIS® V-PRO® 1 Plus
	• The V-PRO® 1 Cycle and the V-PRO® 1 Plus Lumen Cycle can sterilize instruments/devices with the following features:
	  • 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 3 mm or larger and a length of 400 mm or shorter
	  • an inside diameter of 2 mm or larger and a length of 250 mm or shorter
	  • an inside diameter of 1 mm or larger and a length of 125 mm or shorter
	STERIS® V-PRO® maX
	• Lumened and non-lumened instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors.
	• Medical devices, including single, dual and triple channeled rigid and semi-rigid endoscopes, with the following configurations:
	  • Single channeled devices with a stainless lumen that is ≥ 0.77mm internal diameter (ID) and ≤500mm in length
	  • Dual channeled devices with stainless steel lumens that are ≥ 0.77mm ID and ≤ 527mm in length
	  • Triple channeled devices with stainless steel lumens that are
	  • ≥ 1.2 mm ID and ≤ 275 mm in length
	  • ≥ 1.8 mm ID and ≤ 310 mm in length
	  OR
	  • ≥ 2.8 mm ID and ≤ 317 mm in length
	STERIS® V-PRO® maX 2
	• Medical devices, including single, dual and triple channeled rigid and semi-rigid endoscopes, with the following configurations:
	  • Single channeled devices with a stainless lumen that is ≥ 0.77mm internal diameter (ID) and ≤500mm in length
	  • Dual channeled devices with stainless steel lumens that are ≥ 0.77mm ID and ≤ 527mm in length
	  • Triple channeled devices with stainless steel lumens that are
	  • ≥ 1.2 mm ID and ≤ 275 mm in length
	  • ≥ 1.8 mm ID and ≤ 310 mm in length
	  OR
	  • ≥ 2.8 mm ID and ≤ 317 mm in length

Validated Low Temperature Sterilization Products STERIS® V-PRO® 1, STERIS® V-PRO® 1 Plus, STERIS® V-PRO® maX, STERIS® V-PRO® maX 2, and STERIS® V-PRO® 60, Lumen[5] Cycles **Note:** *Refer to the Manufacturer's User's Guide for complete instructions on load and cycle for each STERIS® V-PRO® System. The instructions provided below are not intended to replace the detailed Instructions for Use provided with the STERIS® V-PRO®.*	
STERIS® V-PRO® System Lumen Cycle	**Intended Load**

STERIS® V-PRO® 60	**The V-PRO® 60 sterilizer's Lumen cycle can sterilize:**
	• Instruments with diffusion- restricted spaces such as the hinged portion of forceps and scissors.
	• Non-lumened devices including non-lumened rigid and semi-rigid endoscopes
	• Medical Devices, including single, dual and triple channeled rigid and semi-rigid endoscopes, with the following configurations:
	  • Single or dual lumen devices with stainless steel lumens that are
	  • ≥ 0.77 mm (~ 1/32 in.) internal diameter (ID) and ≤ 410 mm (16-9/64 in.) in length
	  • Triple lumen devices with stainless steel lumens that are
	  • ≥ 1.2 mm (~ 3/64 in.) ID and ≤ 275 mm (~ 10 – 55/64 in.) in length
	  • ≥ 1.8 mm (~ 5/64 in.) ID and ≤ 310 mm (~ 12 – 13/64 in.) in length or
	  • ≥ 2.8 mm (~ 7/64 in.) ID and ≤ 317 mm (~ 12 – 31/64 in.) in length

[5] The Non-Lumen articles can be processed in the Lumen cycle as it takes mixed loads.

Validated Low Temperature Sterilization Products STERIS® V-PRO® 1 Plus, STERIS® V-PRO® maX, STERIS® V-PRO® maX 2, and STERIS® V-PRO® 60, Non-Lumen Cycles **Note:** *Refer to the Manufacturer's User's Guide for complete instructions on load and cycle for each STERIS® V-PRO® System. The instructions provided below are not intended to replace the detailed Instructions for Use provided with the STERIS® V-PRO®.*	
STERIS® V-PRO® System Non-Lumen Cycle	**Intended Load**
STERIS® V-PRO® 1 Plus **STERIS® V-PRO® maX** **STERIS® V-PRO® maX 2**	**STERIS® V-PRO® 1 Plus** The V-PRO® 1 Plus Non-Lumen Cycle can sterilize instruments/devices with the following features: • Non-Lumen instruments including non-lumened instruments with stainless steel diffusion-restricted areas such as the hinged portion of forceps or scissors. **STERIS® V-PRO® maX** The Non-Lumen Cycle can sterilize instruments/devices with the following features: • Non-lumened instruments including non-lumened rigid, semi-rigid and flexible endoscopes and non-lumened instruments with stainless steel diffusion-restricted areas such as the hinged portion of forceps or scissors. **STERIS® V-PRO® maX 2** Non-lumened instruments including non-lumened general medical instruments, non-lumened rigid, semi-rigid and flexible endoscopes.
STERIS® V-PRO® 60	The V-PRO® 60 Non-Lumen Cycle can sterilize instruments/devices with the following features: • Non-lumened devices including non-lumened rigid, semi-rigid and flexible endoscopes and non-lumened devices with stainless steel or titanium diffusion-restricted spaces such as the hinged portion of forceps and scissors.

Validated Low Temperature Sterilization Products STERIS® V-PRO® maX, STERIS® V-PRO® maX 2, and STERI®S V-PRO® 60, Flexible Cycles

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

STERIS® V-PRO® System Flexible Cycle	Intended Load
STERIS® V-PRO® maX **STERIS® V-PRO® maX 2**	**STERIS® V-PRO® maX** The Flexible Cycle can sterilize single or dual lumen surgical flexible endoscopes (such as those used in ENT, Urology and Surgical Care) or bronchoscopes in either of two load configurations: 1. Two flexible endoscopes with a light cord (if not integral to the endoscope) and mat with no additional load[3]. The flexible endoscopes may contain either: • A single lumen that is ≥ 1 mm ID and ≤ 1050 mm in length • Or two lumens with: ◦ One lumen that is ≥ 1 mm ID and ≤ 998 mm in length ◦ And the other lumen that is ≥ 1 mm ID and ≤ 850 mm in length 2. One flexible endoscope with a light cord (if not integral to endoscope) and mat and additional non-lumened instruments including instruments with diffusion-restricted areas such as the hinged portion of forceps or scissors[4]. The flexible endoscopes may contain either: • A single lumen that is ≥ 1 mm ID and ≤ 1050 mm in length • Or two lumens with: ◦ One lumen that is ≥ 1 mm ID and ≤ 998 mm in length And the other lumen that is ≥ 1 mm ID and ≤ 850 mm in length **STERIS® V-PRO® maX 2** The Flexible Cycle can sterilize single or dual lumen surgical flexible endoscopes (such as those used in ENT, Urology and Surgical Care) or bronchoscopes in either of two load configurations: 1. Two flexible endoscopes with a light cord (if not integral to the endoscope) and mat with no additional load. The flexible endoscopes may contain either: • A single lumen that is ≥ 1 mm ID and ≤ 1050 mm in length • Or two lumens with: ◦ One lumen that is ≥ 1 mm ID and ≤ 998 mm in length ◦ And the other lumen that is ≥ 1 mm ID and ≤ 850 mm in length 2. One flexible endoscope with a light cord (if not integral to endoscope) and mat and additional non-lumened instruments. The flexible endoscopes may contain either: • A single lumen that is ≥ 1 mm ID and ≤ 1050 mm in length • Or two lumens with: ◦ One lumen that is ≥ 1 mm ID and ≤ 990 mm in length ◦ And the other lumen that is ≥ 1 mm ID and ≤ 850 mm in length
STERIS® V-PRO® 60	**The V-PRO® 60 sterilizer's 60 flexible cycle can sterilize:** • One flexible surgical endoscope or bronchoscope with a light cord (if not integral to endoscope) and mat without any additional load. The flexible endoscope may be a: ◦ Single or dual lumen device with lumens that are > 1 mm (~3/64 in.) ID and <990 mm (38-63/34 in.) in length

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