September 16, 2024

O&M Halyard, Inc.
Anureet Singh
Regulatory Affairs Manager
9120 Lockwood Blvd
Mechanicsville, Virginia 23116

Re: K234050
Trade/Device Name: HALYARD® ONE-STEP® Sterilization Wrap, HALYARD® QUICK CHECK® Sterilization Wrap, HALYARD® SEQUENTIAL Sterilization Wrap and HALYARD® SMART-FOLD® Sterilization Wrap
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization wrap
Regulatory Class: Class II
Product Code: FRG
Dated: December 21, 2023
Received: August 13, 2024

Dear Anureet Singh:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Stephen A. Anisko -S

Digitally signed by Stephen A. Anisko -S
Date: 2024.09.16 17:19:42 -04'00'

for: Christopher Dugard
Assistant Director
THT4C1: Sterility Devices Team
DHT4C: Division of Infection Control Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K234050

Device Name
HALYARD* SMART-FOLD* Sterilization Wrap

Indications for Use *(Describe)*
HALYARD® SMART-FOLD 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 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.

STERIS V-PRO® Low Temperature Sterilization Systems.
- STERIS® V-PRO® 60 (Lumen, Non-Lumen and Flexible Cycles)
- STERIS® V-PRO® s2 (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)

- Advanced Sterilization Products STERRAD® Sterilization System
  - STERRAD® 100S
  - 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, ULTRA GI Cycle)
  - STERRAD® 100NX® with ALLClear® Technology, (Standard Cycle, Flex Cycle, EXPRESS Cycle, DUO Cycle, ULTRA GI Cycle)

SMART-FOLD Wrap Model Recommendations with Pre-vacuum and EO
Halyard SMART-FOLD Sterilization Wrap: H450
Intended Load**: Moderate to Heavyweight Package (for example: general use medical instruments)
Wrapped Package Content Weights***: 13 lbs.
Halyard SMART-FOLD Sterilization Wrap: H650
Intended Load**: Moderate to Heavyweight Package (for example: general use medical instruments)
Wrapped Package Content Weights***: 25 lbs.

SMART-FOLD Wrap Model Recommendations with ASP STERRAD® Sterilization System - ASP STERRAD® 100S, NX®, NX® with ALLClear® Technology, 100NX® and 100NX® with ALLClear® Technology
Halyard SMART-FOLD Sterilization Wrap: H450
Intended Load**: Moderate to Heavyweight Package (for example: general use medical instruments)
Wrapped Package Content Weights***: 10.7 lbs.
Halyard SMART-FOLD Sterilization Wrap: H650
Intended Load**: Moderate to Heavyweight Package (for example: general use medical instruments)
Wrapped Package Content Weights***: 10.7 lbs.

SMART-FOLD Wrap Model Recommendations with ASP STERRAD® Sterilization System - ASP STERRAD® 100NX® and 100NX® with ALLClear® Technology - ULTRA GI Cycle
Halyard SMART-FOLD Sterilization Wrap: H450
Intended Load**: Moderate to Heavyweight Package (for example: general use medical instruments)
Wrapped Package Content Weights***: 7.7 lbs.

Halyard SMART-FOLD Sterilization Wrap: H650
Intended Load**: Moderate to Heavyweight Package (for example: general use medical instruments)
Wrapped Package Content Weights***: 7.7 lbs.

SMART-FOLD Wrap Model Recommendations with STERIS V-PRO Sterilizers
Halyard SMART-FOLD Sterilization Wrap: H450
Intended Load**: Moderate to Heavyweight Package (for example: general use medical instruments)
Wrapped Package Content Weights***
STERIS® V-PRO® 1, 1Plus, maX, maX 2 Lumen: 13 lbs.
STERIS® V-PRO® 1Plus, maX, maX 2 Non-Lumen: 13 lbs.
STERIS® V-PRO® maX, maX 2 Flexible: 13 lbs.
STERIS® V-PRO® 60, s2 Lumen: 11 lbs.
STERIS® V-PRO® 60, s2 Non-Lumen: 12 lbs.
STERIS® V-PRO® 60, s2 Flexible: 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 additional load.

Halyard SMART-FOLD Sterilization Wrap: H650
Intended Load**: Moderate to Heavyweight Package (for example: general use medical instruments)
Wrapped Package Content Weights***
STERIS® V-PRO® 1, 1Plus, maX, maX 2 Lumen: 19.65 lbs.
STERIS® V-PRO® 1Plus, maX, maX 2 Non-Lumen: 25 lbs
STERIS® V-PRO® maX, maX 2 Flexible: 24 lbs.
STERIS® V-PRO® 60, s2 Lumen: 11 lbs.
STERIS® V-PRO® 60, s2 Non-Lumen: 12 lbs.
STERIS® V-PRO® 60, s2 Flexible: 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 additional load.

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

Validated STERIS® V-PRO® Low Temperature Sterilization Cycles (HALYARD SMART-FOLD)
STERIS® V-PRO® 1 and STERIS® V-PRO® 1 Plus Lumen Cycle Intended Load
• 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
  • ≥ 0.77 mm internal diameter (ID) and ≤ 500mm in length
  • ≥ 1.8 mm ID and ≤ 542 mm 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 and STERIS V-PRO maX 2 Lumen Cycle Intended Load
- Medical devices with the following configurations:
  • Non-lumened instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors.
  • Single, dual or triple channeled devices with stainless steel lumens with
  • An inside diameter of 0.77 mm or larger and a length of 527 mm or shorter

• An inside diameter of 0.8 mm or larger and a length of 542 mm or shorter
• An inside diameter of 0.48 mm or larger and a length of 100 mm or shorter

- Dead end lumen with
• An inside diameter of 1.3 mm or larger and a length of 73 mm or shorter

-Rigid non-metallic lumen (such as those used in endoscope sheaths, take-apart forceps and trocars) with
• An inside diameter of 3 mm or larger and a length of 298 mm or shorter
• An inside diameter of 4 mm or larger and a length of 424 mm or shorter

Validation testing for all lumen sizes was conducted using a maximum of 20 lumens per load. The validation studies were performed using a validation load consisting of two trays with silicone mats for a total weight of 19.65 lbs.

STERIS® V-PRO® 60 and s2 Lumen Cycle Intended Load
- 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 internal diameter (ID) and ≤ 410 mm in length
• ≥ 1.8 mm ID and ≤ 542 mm in length
• ≥Triple lumen 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
The Non-Lumen articles can be processed in the Lumen cycle as it takes mixed loads.

STERIS® V-PRO® 1 Plus Non-Lumen Cycle Intended Load
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 or titanium diffusion-restricted areas such as the hinged portion of forceps or scissors.

STERIS® V-PRO® maX and STERIS® V-PRO® maX 2 Non-Lumen Cycle Intended Load
Non-lumened instruments including non-lumened general medical instruments, non-lumened rigid, semi-rigid and flexible endoscopes.
Non-lumened instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors.
Note: The validation studies (maX and maX 2) were conducted using a validation load consisting of two instrument trays for a total weight of 50 lbs.

STERIS® V-PRO® 60 and s2 Non-Lumen Cycle Intended Load
Instruments/devices with the following features:
- Non-lumened devices including non-lumened rigid, semi-rigid and flexible endoscopes and non-lumened devices with diffusion-restricted spaces such as the hinged portion of forceps and scissors.

STERIS® V-PRO® maX and STERIS® V-PRO® maX 2 Flexible Cycle Intended Load
- Non-lumened instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors.
- 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:
• Two flexible endoscopes with a light cord (if not integral to endoscope) and mat with no additional load*. The flexible endoscopes may contain single or dual channel lumens that have:
• ≥ 1 mm ID and ≤ 1050 mm in length
Or
• One flexible endoscope with a light cord (if not integral to endoscope), endoscope accessories, mat and additional non-lumened instruments.** The flexible endoscope may contain single or dual channel lumens that have:

• An inside diameter of 1 mm or larger and a length of 1050 mm or shorter

Additional instruments may include non-lumened or lumened medical devices with the following configurations:

• Single, dual or triple channel stainless steel lumen that have:

• An inside diameter of 0.48 mm or larger and a length of 100 mm or shorter

* The validation studies were conducted with two flexible endoscopes, each packaged into a tray with silicone mat and light cord (if not integral to endoscope).

** The validation studies were conducted with a flexible endoscope in a tray with endoscope accessories, silicone mat, light cord (if not integral to endoscope) and 5 stainless steel lumens. Also included in the load was a tray with additional instruments and silicone mat for a total weight of 24 lbs.

STERIS® V-PRO® 60 and s2 Flexible Cycle Intended Load

Load 1:

• One flexible surgical endoscope or bronchoscope with a light cord (if not integral to endoscope), mat, and additional load. The flexible endoscope may be a:

• Single or dual lumen device with lumens that are > 1 mm ID and <990 mm in length

Load 2:***

Non-lumened instruments, instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors, and medical devices containing stainless steel lumens with the following dimensions:

• ≥ 0.76 mm ID and ≤ 233 mm in length

• ≥ 1.0 mm ID and ≤ 254 mm in length

• ≥ 1.8 mm ID and ≤ 542 mm in length

*** Additional stainless steel lumens are restricted to 12 lumens

Total load weight is restricted to 11 lbs.

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

ASP STERRAD® 100S Validation Load

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 shortcr 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).

ASP STERRAD® NX® Standard Cycle Validation Load

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).

ASP STERRAD® NX® Advanced Cycle Validation Load

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® 100NX® Standard Cycle Validation Load
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).

ASP STERRAD® 100NX® Flex Cycle Validation Load
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).

ASP STERRAD® 100NX® EXPRESS Cycle Validation Load
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® 100NX® DUO Cycle Validation Load
One or two single-channel flexible endoscopes 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).

ASP STERRAD® 100NX® ULTRA GI Cycle Validation Load
• Hydrogen peroxide compatible flexible multi-channel duodenoscopes, with no more than 4 channels, with lumen dimensions of ≥1mm inner diameter x ≤1500mm in length, or ≥2mm inner diameter x ≤1630mm in length.
• One flexible duodenoscope per tray, and no more than two flexible duodenoscope per cycle
Note 1: The STERRAD 100NX Sterilizer ULTRA GI Cycle was validated using a load weight of 15.4 lbs (2 x 7.7 lbs), one endoscope per shelf.
Note 2: Only duodenoscopes that have been cleared as compatible with vaporized hydrogen peroxide are acceptable. Check STERRAD Sterilizer Cycle Selection table for ULTRA GI Cycle compatible duodenoscopes
Refer to the STERRAD® 100NX® Sterilizer User's Guide for complete instructions on load(s) and cycle(s), including chamber loading instructions (i.e., 15.4 lbs. per load).

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K234050

Device Name
HALYARD* QUICK CHECK* Sterilization Wrap;
HALYARD* ONE-STEP* Sterilization Wrap;
HALYARD* SEQUENTIAL* Sterilization Wrap

Indications for Use *(Describe)*
HALYARD* ONE-STEP, QUICK CHECK and SEQUENTIAL 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® s2 (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)
• 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
• 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® HC80TT Sterilization Cycles (Lumen and Flexible Cycles)
• Stryker Sterizone® VP4 Sterilizer Cycle 1

HALYARD Wrap Model Recommendations***

Halyard Sterilization Wrap: H100
Intended Load: Very light weight package (e.g., towel packs)
Wrapped Package Content Weight****:
Pre-vacuum, Gravity and EO: 3 lbs.
STERIS V-PRO 1, 1Plus, maX, maX 2: 3 lbs.
STERIS V-PRO 60, s2: 3 lbs.
ASP STERRAD 50, 100S, 200, NX®, NX® with ALLClear® Technology, 100NX® and 100NX® with ALLClear® Technology Cycles: 10.7 lbs.
STERILUCENT HC80TT Lumen and Flexible Cycles: 3.4 lbs.
Stryker Sterizone VP4 Sterilizer Cycle 1: 3 lbs.

Halyard Sterilization Wrap: H200
Intended Load: Light weight package (e.g., standard linen packs, telescope with light cord)
Wrapped Package Content Weight****:
Pre-vacuum, Gravity and EO: 6 lbs.
STERIS V-PRO 1, 1Plus, maX, maX 2: 6.5 lbs.

STERIS V-PRO 60, s2: 6.5 lbs.
ASP STERRAD 50, 100S, 200, NX®, NX® with ALLClear® Technology, 100NX® and 100NX® with ALLClear® Technology Cycles: 10.7 lbs.
STERILUCENT HC80TT Lumen and Flexible Cycles: 6 lbs.
Stryker Sterizone VP4 Sterilizer Cycle 1: 6 lbs.

Halyard Sterilization Wrap: H300
Intended Load: Light to moderate weight package (e.g., general use medical instruments)
Wrapped Package Content Weight****:
Pre-vacuum, Gravity and EO: 9 lbs.
STERIS V-PRO 1, 1Plus, maX, maX 2: 9 lbs.
STERIS V-PRO 60, s2: 9 lbs.
ASP STERRAD 50, 100S, 200, NX®, NX® with ALLClear® Technology, 100NX® and 100NX® with ALLClear® Technology Cycles: 10.7 lbs.
STERILUCENT HC80TT Lumen and Flexible Cycles: 9.1 lbs.
Stryker Sterizone VP4 Sterilizer Cycle 1: 9 lbs.

Halyard Sterilization Wrap: H400
Intended Load: Moderate to heavy weight package (e.g., general use medical instruments)
Wrapped Package Content Weight****:
Pre-vacuum, Gravity and EO: 13 lbs.*****
STERIS V-PRO 1, 1Plus, maX, maX 2: 10 lbs.
STERIS V-PRO 60, s2: 12 lbs.
ASP STERRAD 50, 100S, 200, NX®, NX® with ALLClear® Technology, 100NX® and 100NX® with ALLClear® Technology Cycles: 10.7 lbs.
STERILUCENT HC80TT Lumen and Flexible Cycles: 13 lbs.
Stryker Sterizone VP4 Sterilizer Cycle 1: 13 lbs.

Halyard Sterilization Wrap: H500
Intended Load: Heavy weight package (e.g., general use medical instruments)
Wrapped Package Content Weight****:
Pre-vacuum, Gravity and EO: 17 lbs.*****
STERIS V-PRO 1, 1Plus, maX, maX 2: 10 lbs.******
STERIS V-PRO 60, s2: 12 lbs.
ASP STERRAD 50, 100S, 200, NX®, NX® with ALLClear® Technology, 100NX® and 100NX® with ALLClear® Technology Cycles: 10.7 lbs.
STERILUCENT HC80TT Lumen and Flexible Cycles: 16.1 lbs.
Stryker Sterizone VP4 Sterilizer Cycle 1: 17 lbs.

Halyard Sterilization Wrap: H600
Intended Load: Very heavy weight package (e.g., general use medical instruments)
Wrapped Package Content Weight****:
Pre-vacuum, Gravity and EO: 25 lbs.*****
STERIS V-PRO 1, 1Plus, maX, maX 2: 25.5 lbs.******
STERIS V-PRO 60, s2: 12 lbs.
ASP STERRAD 50, 100S, 200, NX®, NX® with ALLClear® Technology, 100NX® and 100NX® with ALLClear® Technology Cycles: 10.7 lbs.
STERILUCENT HC80TT Lumen and Flexible Cycles: 26 lbs. (Lumen Cycle) 25 lbs. (Flexible Cycle)
Stryker Sterizone VP4 Sterilizer Cycle 1: 25 lbs.*******

*** 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.

**** 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).
***** 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 H400, H500, and H600 wraps have been validated for sterilant penetration with up to 3 lbs. of non-fluid resistant linen.
****** The H500 and H600 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.
******* Total load weight shall not exceed 75 lbs., inclusive of the containers/packaging weight but excluding the 25 lb. loading rack.

Validation Load Composition
STERIS V-PRO 1 and STERIS V-PRO 1 Plus Lumen Cycle Intended Load
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 channeled devices with stainless steel lumens with
• An inside diameter of 0.77 mm or larger and a length of 500 mm or shorter
• An inside diameter of 1.8 mm or larger and a length of 542 mm or shorter
• Dual channeled devices with stainless steel lumens with
• An inside diameter of 0.77 mm or larger and a length of 527 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

STERIS V-PRO maX and STERIS V-PRO maX2 Lumen Cycle Intended Load
†Medical devices with the following configurations:
• Non-lumened instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors
• Single, dual or triple channeled devices with stainless steel lumens with
• An inside diameter of 0.77 mm or larger and a length of 527 mm or shorter
• An inside diameter of 0.8 mm or larger and a length of 542 mm or shorter
• An inside diameter of 0.48 mm or larger and a length of 100 mm or shorter
• Dead end lumen with
• An inside diameter of 1.3 mm or larger and a length of 73 mm or shorter
• Rigid non-metallic lumen (such as those used in endoscope sheaths, take-apart forceps and trocars) with
• An inside diameter of 3 mm or larger and a length of 298 mm or shorter
• An inside diameter of 4 mm or larger and a length of 424 mm or shorter
† Validation testing for all lumen sizes was conducted using a maximum of 20 lumens per load. Hospital loads should not exceed the maximum number of lumens validated by this testing. The validation studies were performed using a validation load consisting of two trays with silicone mats for a total weight of 19.65 lbs.

STERIS V-PRO 60 and s2 Lumen Cycle Intended Load
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
• An inside diameter of 1.8 mm or larger and a length of 542 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
• An inside diameter of 2.8 mm or larger and a length of 317 mm or shorter
Total load weight restricted to 11lbs.

STERIS V-PRO 1 Plus Non-Lumen Cycle Intended Load
Non-lumened instruments including non-lumened general medical instruments, non-lumened rigid, semi-rigid and flexible endoscopes and non-lumened instruments with stainless steel or titanium diffusion-restricted spaces such as the hinged portion of forceps and scissors.
STERIS V-PRO maX and STERIS V-PRO maX2 Non-Lumen Cycle Intended Load
Non-lumened instruments including non-lumened general medical instruments, non-lumened rigid, semi-rigid and flexible endoscopes.
Non-lumened instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors.
Note: The validation studies were conducted using a validation load consisting of two instrument trays for a total weight of 50 lbs.

STERIS® V-PRO® 60 and s2 Non-Lumen Cycle Intended Load
Metal and non-metal non-lumened medical devices including non-lumened rigid, semi-rigid and flexible endoscopes and medical devices with diffusion-restricted spaces such as the hinged portion of forceps or scissors.
Total load weight is restricted to 25lbs

STERIS V-PRO maX and STERIS V-PRO maX 2 Flexible Cycle Intended Load
Non-lumened instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors.
Single or dual lumen surgical flexible endoscopes (such as those used in ENT, Urology and Surgical Care) and bronchoscopes in either of the two configurations:
Two flexible endoscopes with a light cord (if not integral to endoscope) and mat with no additional load.* The flexible endoscopes may contain single or dual channel lumens that have:
• An inside diameter of 1 mm or larger and a length of 1050 mm or shorter
OR
One flexible endoscope with a light cord (if not integral to endoscope), endoscope accessories, mat and additional non-lumened instruments.** The flexible endoscope may contain single or dual channel lumens that have:
• An inside diameter of 1 mm or larger and a length of 1050 mm or shorter
Additional instruments may include non-lumened or lumened medical devices with the following configurations:
Single, dual or triple channel stainless steel lumen that have:
• An inside diameter of 0.48 mm or larger and a length of 100 mm or shorter
* The validation studies were conducted with two flexible endoscopes, each packaged into a tray with silicone mat and light cord (if not integral to endoscope).
** The validation studies were conducted with a flexible endoscope in a tray with endoscope accessories, silicone mat, light cord (if not integral to endoscope) and 5 stainless steel lumens. Also included in the load was a tray with additional instruments and silicone mat for a total weight of 24 lbs.

STERIS V-PRO 60 and s2 Flexible Cycle Intended Load
Load 1:
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.
Load 2*:
Non-lumened instrument, instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors, and medical devices containing stainless steel lumens with the following dimensions:
• An inside diameter of 0.76 mm or larger and a length of 233 mm or shorter
• An inside diameter of 1.0 mm or larger and a length of 254 mm or shorter
• An inside diameter of 1.8 mm or larger and a length of 542 mm or shorter
*Additional stainless steel lumens are restricted to 12 lumens
Total load weight is restricted to 11 lbs.

Sterilucent HC 80TT Hydrogen Peroxide Sterilizer Lumen Cycle Validation Load
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.)

Sterilucent HC 80TT Hydrogen Peroxide Sterilizer Flexible Cycle Validation Load
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;
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.)

ASP STERRAD® 50 Validation Load
Reusable metal and non-metal medical devices, including up to 10 lumens of the folloving 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 or 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).

ASP STERRAD® 100S Validation Load
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).

ASP STERRAD® 200 Validation Load
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® NX® Standard Cycle Validation Load
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).

ASP STERRAD® NX® Advanced Cycle Validation Load
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® 100NX® Standard Cycle Validation Load
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).

ASP STERRAD® 100NX® Flex Cycle Validation Load
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).

ASP STERRAD® 100NX® EXPRESS Cycle Validation Load
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® 100NX® DUO Cycle Validation Load
One or two single-channel flexible endoscopes 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).

Stryker Sterizone VP4 Sterilizer Cycle 1 Validation Load
General Instruments (H100*, H200, H300, H400, H500, H600*)
1) Load consisted of three (3) trays each containing three (3) lbs. of general medical instruments. The load included general devices representing the following geometries:
Box-lock hinge
Pivot hinge
Luer-lock
Testing was performed with trays wrapped in H100 sterilization wrap.

Load #7** - Consisted of three (3) trays each containing 25 lb of general medical instruments, for a total of 75 lb per load (excluding the loading rack). The load included general devices representing the following geometries:
Box-lock hinge
Pivot hinge
Luer-lock
Testing was performed with trays wrapped in H600 sterilization wrap.

Rigid Channel Instruments (H400*, H500, H600*)
Load #4*** - Consisted of 15 lumens from rigid and semi-rigid channeled devices. The load included:
• Three (3) double channel (six (6) lumens) semi-rigid endoscopes (ureteroscope 0.7 mm x 500 mm and 1.1 mm x 500 mm) were packaged in three (3) sterilization trays including appropriate silicone brackets.

• Additional rigid channel instruments (nine (9) lumens) were added.
Testing was performed with trays wrapped in H400 and H600 sterilization wrap.

Single and Double Channel Flexible Endoscopes (H400*, H500, H600*)
Load #8** - Consisted of five (5) lumens from single and double channel flexible endoscopes. The load included:
• Two (2) double channel flexible endoscopes (ureteroscope) with inside diameter of 1 mm and lengths of 850 mm and 989 mm;
• One (1) single channel flexible endoscope (ureteroscope) with inside diameter of 1 mm and length of 850 mm.
• The endoscopes were individually packaged in sterilization trays, including appropriate silicone brackets.
Testing was performed with trays wrapped in H400 and H600 sterilization wrap.

Multi-Channel Flexible Endoscopes (H400*, H500, H600*)
Load #9** - Consisted of one (1) multichannel flexible endoscope with four (4) channels. The load included:
• One (1) multi flexible endoscope (colonoscope) with no more than four (4) channels having inside diameter of 1.2 mm and lengths of 1955 mm or inside diameter of 1.45 mm and lengths of 3500 mm, packaged individually in a sterilization tray.
Testing was performed with trays wrapped in H400 and H600 sterilization wrap.

* Indicates the bracketed grades for validation testing.
** Representative STERIZONE® VP4 Sterilizer Cycle 1 Validation Load from K172191.
*** HALYARD ONE-STEP* and QUICK CHECK* Sterilization Wrap are comprised of two sheets of HALYARD* Sequential Sterilization Wrap ultrasonically bonded together on two sides. Therefore, these grades are applicable to HALYARD ONE-STEP*, HALYARD* QUICK CHECK* and Sequential Sterilization Wrap.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Submitter: O&M Halyard, Inc.
9120 Lockwood Boulevard
Mechanicsville, VA 23116
Phone: 804-723-7000/800-488-8850
Fax: 804-723-7100

Regulatory Contact: Anureet Singh
Regulatory Affairs Manager
O&M Halyard, Inc.
1220 Old Alpharetta Rd
Suite 320
Alpharetta, GA 30005

Date of Summary: 16 September 2024

Device Trade Name: HALYARD* ONE-STEP* Sterilization Wrap, HALYARD* QUICK CHECK* Sterilization Wrap, HALYARD* SEQUENTIAL Sterilization Wrap and HALYARD* SMART-FOLD* Sterilization Wrap

Common Name: Sterilization Wrap

Classification Name: Sterilization wrap (21 CFR 880.6850, Product Code FRG)

Predicate Device: K214007 (ONE-STEP/QUICK CHECK/SEQUENTIAL Sterilization Wrap)

Device Description: HALYARD SEQUENTIAL 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 ONE-STEP, HALYARD QUICK CHECK and HALYARD SMART-FOLD Sterilization Wraps are comprised of two sheets of HALYARD* SEQUENTIAL Sterilization Wrap. This allows for convenient wrapping with two sheets simultaneously.

The HALYARD ONE-STEP, QUICK CHECK and HALYARD SMART-FOLD Sterilization Wraps are intended to enclose another medical device that is to be sterilized by a healthcare provider.

Indication for Use (QUICK CHECK, ONE-STEP and SEQUENTIAL):

HALYARD ONE-STEP, QUICK CHECK and SEQUENTIAL Sterilization Wraps are intended 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® s2 (Lumen, Non-Lumen and Flexible Cycles)
• STERIS V-PRO® 1 (Lumen Cycle)
• STERIS V-PRO® 1 Plus (Lumen and Non-Lumen Cycles)
• STERIS V-PRO® maX (Lumen, Non-Lumen and Flexible Cycles)
• STERIS V-PRO® maX 2 (Lumen, Non-Lumen and Flexible Cycles)

• Gravity steam at 250°F/121°C for 30 minutes (25 minute dry time for Models 100, 200 and 300 and 30 minute dry time for Models 400, 500 and 600)

• Advanced Sterilization Products STERRAD® Sterilization System
• 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® HC80TT Sterilization Cycles (Lumen and Flexible Cycles)

• Stryker Sterizone® VP4 Sterilizer Cycle 1

HALYARD Wrap Model Recommendations***

Halyard Sterilization Wrap: H100
Intended Load: Very light weight package (e.g., towel packs)
Wrapped Package Content Weight****:
Pre-vacuum, Gravity and EO: 3 lbs.
STERIS V-PRO 1, 1Plus, maX, maX 2: 3 lbs.
STERIS V-PRO 60, s2: 3 lbs.
ASP STERRAD 50, 100S, 200, NX®, NX® with ALLClear® Technology, 100NX® and 100NX® with ALLClear® Technology Cycles: 10.7 lbs.
STERILUCENT HC80TT Lumen and Flexible Cycles: 3.4 lbs.
Stryker Sterizone VP4 Sterilizer Cycle 1: 3 lbs.

Halyard Sterilization Wrap: H200
Intended Load: Light weight package (e.g., standard linen packs, telescope with light cord)
Wrapped Package Content Weight****:
Pre-vacuum, Gravity and EO: 6 lbs.
STERIS V-PRO 1, 1Plus, maX, maX 2: 6.5 lbs.
STERIS V-PRO 60, s2: 6.5 lbs.
ASP STERRAD 50, 100S, 200, NX®, NX® with ALLClear® Technology, 100NX® and 100NX® with ALLClear® Technology Cycles: 10.7 lbs.
STERILUCENT HC80TT Lumen and Flexible Cycles: 6 lbs.
Stryker Sterizone VP4 Sterilizer Cycle 1: 6 lbs.

Halyard Sterilization Wrap: H300
Intended Load: Light to moderate weight package (e.g., general use medical instruments)
Wrapped Package Content Weight****:
Pre-vacuum, Gravity and EO: 9 lbs.
STERIS V-PRO 1, 1Plus, maX, maX 2: 9 lbs.
STERIS V-PRO 60, s2: 9 lbs.
ASP STERRAD 50, 100S, 200, NX®, NX® with ALLClear® Technology, 100NX® and 100NX® with ALLClear® Technology Cycles: 10.7 lbs.
STERILUCENT HC80TT Lumen and Flexible Cycles: 9.1 lbs.
Stryker Sterizone VP4 Sterilizer Cycle 1: 9 lbs.

Halyard Sterilization Wrap: H400
Intended Load: Moderate to heavy weight package (e.g., general use medical instruments)
Wrapped Package Content Weight****:
Pre-vacuum, Gravity and EO: 13 lbs.*****
STERIS V-PRO 1, 1Plus, maX, maX 2: 10 lbs.
STERIS V-PRO 60, s2: 12 lbs.
ASP STERRAD 50, 100S, 200, NX®, NX® with ALLClear® Technology, 100NX® and 100NX® with ALLClear® Technology Cycles: 10.7 lbs.
STERILUCENT HC80TT Lumen and Flexible Cycles: 13 lbs.
Stryker Sterizone VP4 Sterilizer Cycle 1: 13 lbs.

Halyard Sterilization Wrap: H500
Intended Load: Heavy weight package (e.g., general use medical instruments)
Wrapped Package Content Weight****:
Pre-vacuum, Gravity and EO: 17 lbs.*****
STERIS V-PRO 1, 1Plus, maX, maX 2: 10 lbs.******
STERIS V-PRO 60, s2: 12 lbs.
ASP STERRAD 50, 100S, 200, NX®, NX® with ALLClear® Technology, 100NX® and 100NX® with ALLClear® Technology Cycles: 10.7 lbs.
STERILUCENT HC80TT Lumen and Flexible Cycles: 16.1 lbs.
Stryker Sterizone VP4 Sterilizer Cycle 1: 17 lbs.

Halyard Sterilization Wrap: H600
Intended Load: Very heavy weight package (e.g., general use medical instruments)
Wrapped Package Content Weight****:

Pre-vacuum, Gravity and EO: 25 lbs.*****
STERIS V-PRO 1, 1Plus, maX, maX 2: 25.5 lbs.******
STERIS V-PRO 60, s2: 12 lbs.
ASP STERRAD 50, 100S, 200, NX®, NX® with ALLClear® Technology, 100NX® and 100NX® with ALLClear® Technology Cycles: 10.7 lbs.
STERILUCENT HC80TT Lumen and Flexible Cycles: 26 lbs. (Lumen Cycle) 25 lbs. (Flexible Cycle)
Stryker Sterizone VP4 Sterilizer Cycle 1: 25 lbs.*******

*** 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.
**** 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).
***** 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 H400, H500, and H600 wraps have been
validated for sterilant penetration with up to 3 lbs. of non-fluid resistant linen.
****** The H500 and H600 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.
******* Total load weight shall not exceed 75 lbs., inclusive of the containers/packaging weight but excluding the 25 lb. loading rack.

Validation Load Composition
STERIS V-PRO 1 and STERIS V-PRO 1 Plus Lumen Cycle Intended Load
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 channeled devices with stainless steel lumens with
• An inside diameter of 0.77 mm or larger and a length of 500 mm or shorter
• An inside diameter of 1.8 mm or larger and a length of 542 mm or shorter
• Dual channeled devices with stainless steel lumens with
• An inside diameter of 0.77 mm or larger and a length of 527 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

STERIS V-PRO maX and STERIS V-PRO maX2 Lumen Cycle Intended Load
†Medical devices with the following configurations:
• Non-lumened instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors
• Single, dual or triple channeled devices with stainless steel lumens with
• An inside diameter of 0.77 mm or larger and a length of 527 mm or shorter

• An inside diameter of 0.8 mm or larger and a length of 542 mm or shorter
• An inside diameter of 0.48 mm or larger and a length of 100 mm or shorter
• Dead end lumen with
• An inside diameter of 1.3 mm or larger and a length of 73 mm or shorter
• Rigid non-metallic lumen (such as those used in endoscope sheaths, take-apart forceps and trocars) with
• An inside diameter of 3 mm or larger and a length of 298 mm or shorter
• An inside diameter of 4 mm or larger and a length of 424 mm or shorter
† Validation testing for all lumen sizes was conducted using a maximum of 20 lumens per load. Hospital loads should not exceed the maximum number of lumens validated by this testing. The validation studies were performed using a validation load consisting of two trays with silicone mats for a total weight of 19.65 lbs.

STERIS V-PRO 60 and s2 Lumen Cycle Intended Load
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
• An inside diameter of 1.8 mm or larger and a length of 542 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
• An inside diameter of 2.8 mm or larger and a length of 317 mm or shorter
Total load weight restricted to 11lbs.

STERIS V-PRO 1 Plus Non-Lumen Cycle Intended Load
Non-lumened instruments including non-lumened general medical instruments, non-lumened rigid, semi-rigid and flexible endoscopes and non-lumened instruments with stainless steel or titanium diffusion-restricted spaces such as the hinged portion of forceps and scissors.
STERIS V-PRO maX and STERIS V-PRO maX2 Non-Lumen Cycle Intended Load
Non-lumened instruments including non-lumened general medical instruments, non-lumened rigid, semi-rigid and flexible endoscopes.
Non-lumened instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors.
Note: The validation studies were conducted using a validation load consisting of two instrument trays for a total weight of 50 lbs.

STERIS® V-PRO® 60 and s2 Non-Lumen Cycle Intended Load
Metal and non-metal non-lumened medical devices including non-lumened rigid, semi-rigid and flexible endoscopes and medical devices with diffusion-restricted spaces such as the hinged portion of forceps or scissors.
Total load weight is restricted to 25lbs

STERIS V-PRO maX and STERIS V-PRO maX 2 Flexible Cycle Intended Load
Non-lumened instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors.

Single or dual lumen surgical flexible endoscopes (such as those used in ENT, Urology and Surgical Care) and bronchoscopes in either of the two configurations:
Two flexible endoscopes with a light cord (if not integral to endoscope) and mat with no additional load.*
The flexible endoscopes may contain single or dual channel lumens that have:
• An inside diameter of 1 mm or larger and a length of 1050 mm or shorter
OR
One flexible endoscope with a light cord (if not integral to endoscope), endoscope accessories, mat and additional non-lumened instruments.** The flexible endoscope may contain single or dual channel lumens that have:
• An inside diameter of 1 mm or larger and a length of 1050 mm or shorter
Additional instruments may include non-lumened or lumened medical devices with the following configurations:
Single, dual or triple channel stainless steel lumen that have:
• An inside diameter of 0.48 mm or larger and a length of 100 mm or shorter
* The validation studies were conducted with two flexible endoscopes, each packaged into a tray with silicone mat and light cord (if not integral to endoscope).
** The validation studies were conducted with a flexible endoscope in a tray with endoscope accessories, silicone mat, light cord (if not integral to endoscope) and 5 stainless steel lumens. Also included in the load was a tray with additional instruments and silicone mat for a total weight of 24 lbs.

STERIS V-PRO 60 and s2 Flexible Cycle Intended Load
Load 1:
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.
Load 2*:
Non-lumened instrument, instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors, and medical devices containing stainless steel lumens with the following dimensions:
• An inside diameter of 0.76 mm or larger and a length of 233 mm or shorter
• An inside diameter of 1.0 mm or larger and a length of 254 mm or shorter
• An inside diameter of 1.8 mm or larger and a length of 542 mm or shorter
*Additional stainless steel lumens are restricted to 12 lumens
Total load weight is restricted to 11 lbs.

Sterilucent HC 80TT Hydrogen Peroxide Sterilizer Lumen Cycle Validation Load
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.)

Sterilucent HC 80TT Hydrogen Peroxide Sterilizer Flexible Cycle Validation Load

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;
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.)

ASP STERRAD® 50 Validation Load
Reusable metal and non-metal medical devices, including up to 10 lumens of the folloving 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 or 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).

ASP STERRAD® 100S Validation Load
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).

ASP STERRAD® 200 Validation Load
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® NX® Standard Cycle Validation Load
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).

ASP STERRAD® NX® Advanced Cycle Validation Load
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® 100NX® Standard Cycle Validation Load
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).

ASP STERRAD® 100NX® Flex Cycle Validation Load
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).

ASP STERRAD® 100NX® EXPRESS Cycle Validation Load
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® 100NX® DUO Cycle Validation Load
One or two single-channel flexible endoscopes 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).

Stryker Sterizone VP4 Sterilizer Cycle 1 Validation Load
General Instruments (H100*, H200, H300, H400, H500, H600*)
1) Load consisted of three (3) trays each containing three (3) lbs. of general medical instruments. The load included general devices representing the following geometries:
Box-lock hinge
Pivot hinge
Luer-lock
Testing was performed with trays wrapped in H100 sterilization wrap.

Load #7** - Consisted of three (3) trays each containing 25 lb of general medical instruments, for a total of 75 lb per load (excluding the loading rack). The load included general devices representing the following geometries:
Box-lock hinge
Pivot hinge
Luer-lock
Testing was performed with trays wrapped in H600 sterilization wrap.

Rigid Channel Instruments (H400*, H500, H600*)
Load #4*** - Consisted of 15 lumens from rigid and semi-rigid channeled devices. The load included:
• Three (3) double channel (six (6) lumens) semi-rigid endoscopes (ureteroscope 0.7 mm x 500 mm and 1.1 mm x 500 mm) were packaged in three (3) sterilization trays including appropriate silicone brackets.
• Additional rigid channel instruments (nine (9) lumens) were added.
Testing was performed with trays wrapped in H400 and H600 sterilization wrap.

Single and Double Channel Flexible Endoscopes (H400*, H500, H600*)
Load #8** - Consisted of five (5) lumens from single and double channel flexible endoscopes. The load included:
• Two (2) double channel flexible endoscopes (ureteroscope) with inside diameter of 1 mm and lengths of 850 mm and
989 mm;
• One (1) single channel flexible endoscope (ureteroscope) with inside diameter of 1 mm and length of 850 mm.
• The endoscopes were individually packaged in sterilization trays, including appropriate silicone brackets.

Testing was performed with trays wrapped in H400 and H600 sterilization wrap.

Multi-Channel Flexible Endoscopes (H400*, H500, H600*)
Load #9** - Consisted of one (1) multichannel flexible endoscope with four (4) channels. The load included:
• One (1) multi flexible endoscope (colonoscope) with no more than four (4) channels having inside diameter of 1.2 mm and lengths of 1955 mm or inside diameter of 1.45 mm and lengths of 3500 mm, packaged individually in a sterilization tray.
Testing was performed with trays wrapped in H400 and H600 sterilization wrap.

* Indicates the bracketed grades for validation testing.
** Representative STERIZONE® VP4 Sterilizer Cycle 1 Validation Load from K172191.
*** HALYARD ONE-STEP* and QUICK CHECK* Sterilization Wrap are comprised of two sheets of HALYARD* Sequential Sterilization Wrap ultrasonically bonded together on two sides. Therefore, these grades are applicable to HALYARD ONE-STEP*, HALYARD* QUICK CHECK* and Sequential Sterilization Wrap.

Indication For Use (SMART-FOLD):

HALYARD® SMART-FOLD 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 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.

-STERIS V-PRO® Low Temperature Sterilization Systems.
- STERIS® V-PRO® 60 (Lumen, Non-Lumen and Flexible Cycles)
- STERIS® V-PRO® s2 (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)

- Advanced Sterilization Products STERRAD® Sterilization System
- STERRAD® 100S
- 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, ULTRA GI Cycle)
- STERRAD® 100NX® with ALLClear® Technology, (Standard Cycle, Flex Cycle, EXPRESS Cycle, DUO Cycle, ULTRA GI Cycle)

SMART-FOLD Wrap Model Recommendations with Pre-vacuum and EO
Halyard SMART-FOLD Sterilization Wrap: H450
Intended Load**: Moderate to Heavyweight Package (for example: general use medical instruments)
Wrapped Package Content Weights***: 13 lbs.
Halyard SMART-FOLD Sterilization Wrap: H650
Intended Load**: Moderate to Heavyweight Package (for example: general use medical instruments)
Wrapped Package Content Weights***: 25 lbs.

SMART-FOLD Wrap Model Recommendations with ASP STERRAD® Sterilization System - ASP STERRAD® 100S, NX®, NX® with ALLClear® Technology, 100NX® and 100NX® with ALLClear® Technology
Halyard SMART-FOLD Sterilization Wrap: H450
Intended Load**: Moderate to Heavyweight Package (for example: general use medical instruments)
Wrapped Package Content Weights***: 10.7 lbs.
Halyard SMART-FOLD Sterilization Wrap: H650
Intended Load**: Moderate to Heavyweight Package (for example: general use medical instruments)
Wrapped Package Content Weights***: 10.7 lbs.

SMART-FOLD Wrap Model Recommendations with ASP STERRAD® Sterilization System - ASP STERRAD® 100NX® and 100NX® with ALLClear® Technology - ULTRA GI Cycle
Halyard SMART-FOLD Sterilization Wrap: H450
Intended Load**: Moderate to Heavyweight Package (for example: general use medical instruments)

Wrapped Package Content Weights***: 7.7 lbs.
Halyard SMART-FOLD Sterilization Wrap: H650
Intended Load**: Moderate to Heavyweight Package (for example: general use medical instruments)
Wrapped Package Content Weights***: 7.7 lbs.

SMART-FOLD Wrap Model Recommendations with STERIS V-PRO Sterilizers
Halyard SMART-FOLD Sterilization Wrap: H450
Intended Load**: Moderate to Heavyweight Package (for example: general use medical instruments)
Wrapped Package Content Weights***
STERIS® V-PRO® 1, 1Plus, maX, maX 2 Lumen: 13 lbs.
STERIS® V-PRO® 1Plus, maX, maX 2 Non-Lumen: 13 lbs.
STERIS® V-PRO® maX, maX 2 Flexible: 13 lbs.
STERIS® V-PRO® 60, s2 Lumen: 11 lbs.
STERIS® V-PRO® 60, s2 Non-Lumen: 12 lbs.
STERIS® V-PRO® 60, s2 Flexible: 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 additional load.

Halyard SMART-FOLD Sterilization Wrap: H650
Intended Load**: Moderate to Heavyweight Package (for example: general use medical instruments)
Wrapped Package Content Weights***
STERIS® V-PRO® 1, 1Plus, maX, maX 2 Lumen: 19.65 lbs.
STERIS® V-PRO® 1Plus, maX, maX 2 Non-Lumen: 25 lbs
STERIS® V-PRO® maX, maX 2 Flexible: 24 lbs.
STERIS® V-PRO® 60, s2 Lumen: 11 lbs.
STERIS® V-PRO® 60, s2 Non-Lumen: 12 lbs.
STERIS® V-PRO® 60, s2 Flexible: 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 additional load.

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

Validated STERIS® V-PRO® Low Temperature Sterilization Cycles (HALYARD SMART-FOLD)
STERIS® V-PRO® 1 and STERIS® V-PRO® 1 Plus Lumen Cycle Intended Load
• 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
  • ≥ 0.77 mm internal diameter (ID) and ≤ 500mm in length
  • ≥ 1.8 mm ID and ≤ 542 mm 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 and STERIS V-PRO maX 2 Lumen Cycle Intended Load
- Medical devices with the following configurations:
  • Non-lumened instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors.
  • Single, dual or triple channeled devices with stainless steel lumens with
  • An inside diameter of 0.77 mm or larger and a length of 527 mm or shorter
  • An inside diameter of 0.8 mm or larger and a length of 542 mm or shorter
  • An inside diameter of 0.48 mm or larger and a length of 100 mm or shorter

- Dead end lumen with
  • An inside diameter of 1.3 mm or larger and a length of 73 mm or shorter

-Rigid non-metallic lumen (such as those used in endoscope sheaths, take-apart forceps and trocars) with
  • An inside diameter of 3 mm or larger and a length of 298 mm or shorter
  • An inside diameter of 4 mm or larger and a length of 424 mm or shorter

Validation testing for all lumen sizes was conducted using a maximum of 20 lumens per load. The validation studies were performed using a validation load consisting of two trays with silicone mats for a total weight of 19.65 lbs.

STERIS® V-PRO® 60 and s2 Lumen Cycle Intended Load
- 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 internal diameter (ID) and ≤ 410 mm in length
  • ≥ 1.8 mm ID and ≤ 542 mm in length
  • ≥Triple lumen 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

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

STERIS® V-PRO® 1 Plus Non-Lumen Cycle Intended Load
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 or titanium diffusion-restricted areas such as the hinged portion of forceps or scissors.

STERIS® V-PRO® maX and STERIS® V-PRO® maX 2 Non-Lumen Cycle Intended Load

Non-lumened instruments including non-lumened general medical instruments, non-lumened rigid, semi-rigid and flexible endoscopes.
Non-lumened instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors.
Note: The validation studies (maX and maX 2) were conducted using a validation load consisting of two instrument trays for a total weight of 50 lbs.

STERIS® V-PRO® 60 and s2 Non-Lumen Cycle Intended Load
Instruments/devices with the following features:
- Non-lumened devices including non-lumened rigid, semi-rigid and flexible endoscopes and non-lumened devices with diffusion-restricted spaces such as the hinged portion of forceps and scissors.

STERIS® V-PRO® maX and STERIS® V-PRO® maX 2 Flexible Cycle Intended Load
- Non-lumened instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors.
- 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:
  • Two flexible endoscopes with a light cord (if not integral to endoscope) and mat with no additional load*. The flexible endoscopes may contain single or dual channel lumens that have:
    • ≥ 1 mm ID and ≤ 1050 mm in length
  Or
  • One flexible endoscope with a light cord (if not integral to endoscope), endoscope accessories, mat and additional non-lumened instruments.** The flexible endoscope may contain single or dual channel lumens that have:
    • An inside diameter of 1 mm or larger and a length of 1050 mm or shorter
Additional instruments may include non-lumened or lumened medical devices with the following configurations:
  • Single, dual or triple channel stainless steel lumen that have:
    • An inside diameter of 0.48 mm or larger and a length of 100 mm or shorter
* The validation studies were conducted with two flexible endoscopes, each packaged into a tray with silicone mat and light cord (if not integral to endoscope).
** The validation studies were conducted with a flexible endoscope in a tray with endoscope accessories, silicone mat, light cord (if not integral to endoscope) and 5 stainless steel lumens. Also included in the load was a tray with additional instruments and silicone mat for a total weight of 24 lbs.

STERIS® V-PRO® 60 and s2 Flexible Cycle Intended Load
Load 1:
• One flexible surgical endoscope or bronchoscope with a light cord (if not integral to endoscope), mat, and additional load. The flexible endoscope may be a:
• Single or dual lumen device with lumens that are > 1 mm ID and <990 mm in length

Load 2:***
Non-lumened instruments, instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors, and medical devices containing stainless steel lumens with the following dimensions:
• ≥ 0.76 mm ID and ≤ 233 mm in length
• ≥ 1.0 mm ID and ≤ 254 mm in length

• ≥ 1.8 mm ID and ≤ 542 mm in length
*** Additional stainless steel lumens are restricted to 12 lumens
Total load weight is restricted to 11 lbs.

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

ASP STERRAD® 100S Validation Load
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 shortcr 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).

ASP STERRAD® NX® Standard Cycle Validation Load
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).

ASP STERRAD® NX® Advanced Cycle Validation Load
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® 100NX® Standard Cycle Validation Load
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).

ASP STERRAD® 100NX® Flex Cycle Validation Load
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).

ASP STERRAD® 100NX® EXPRESS Cycle Validation Load
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® 100NX® DUO Cycle Validation Load
One or two single-channel flexible endoscopes 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).

ASP STERRAD® 100NX® ULTRA GI Cycle Validation Load
• Hydrogen peroxide compatible flexible multi-channel duodenoscopes, with no more than 4 channels, with lumen dimensions of ≥1mm inner diameter x ≤1500mm in length, or ≥2mm inner diameter x ≤1630mm in length.
• One flexible duodenoscope per tray, and no more than two flexible duodenoscope per cycle
Note 1: The STERRAD 100NX Sterilizer ULTRA GI Cycle was validated using a load weight of 15.4 lbs (2 x 7.7 lbs), one endoscope per shelf.
Note 2: Only duodenoscopes that have been cleared as compatible with vaporized hydrogen peroxide are acceptable. Check STERRAD Sterilizer Cycle Selection table for ULTRA GI Cycle compatible duodenoscopes
Refer to the STERRAD® 100NX® Sterilizer User's Guide for complete instructions on load(s) and cycle(s), including chamber loading instructions (i.e., 15.4 lbs. per load).

Technological Characteristics Comparison Table:

	Subject **HALYARD ONE-STEP, QUICK CHECK, SEQUENTIAL and SMART-FOLD Sterilization Wrap**	**Predicate** **HALYARD ONE-STEP and QUICK CHECK Sterilization Wrap (K214007)**	**Comparison**
Manufacturer	O&M Halyard, Inc.	O&M Halyard, Inc.	Same
Device Model Numbers	HALYARD ONE-STEP, QUICK CHECK, and SEQUENTIAL H100 H200 H300 H400 H500 H600 HALYARD SMART-FOLD H450 H650	H100 H200 H300 H400 H500 H600	Similar. The HALYARD ONE-STEP and QUICK CHECK devices are physically identical, differing only in validated cycles.
Common or Usual Name	Sterilization Wrap	Sterilization Wrap	Same
Classification	21 CFR 880.6850	21 CFR 880.6850	Same
Class	II	II	Same
Product Code	FRG	FRG	Same
Indication for Use (Details of validated cycles not shown for brevity)	HALYARD ONE-STEP, QUICK CHECK and SEQUENTIAL Sterilization Wraps are intended to enclose another medical device that is to be sterilized by a healthcare provider (Refer to pages 2 to10 for complete Indications For Use) HALYARD SMART-FOLD Sterilization Wraps are intended to be used to enclose another medical device that is to be sterilized by a healthcare provider. (Refer to pages 11 to 16 for complete Indications For Use)	HALYARD ONE-STEP and QUICK CHECK Sterilization Wraps are intended to enclose another medical device that is to be sterilized by a healthcare provider using the Stryker Sterizone VP4 Sterilizer Cycle 1. The HALYARD ONE-STEP and QUICK CHECK Sterilization Wraps are intended to allow sterilization of the enclosed devices by the Stryker Sterizone VP4 Sterilizer Cycle 1.	Similar. The subject device has been validated for additional cycles, while the predicate has been validated for Stryker Sterizone VP4 Cycle 1.
Validated Sterilization Cycles	• Pre-vacuum steam (270°F/132°C for 4 minutes) • 100% ethylene oxide (EO) (concentration of 725-735 mg/L at 131°F/55°C and 40%-80% relative humidity for 60 minutes) V-PRO® Low Temperature Sterilization System: o Lumen Cycle o Non-Lumen Cycle o Flexible Cycle	Stryker Sterizone VP4 Sterilizer Cycle 1	Similar. The cycles are appropriate for sterilizing similar medical devices. The subject device includes additional cycles previously cleared for physically identical wraps, including the predicate K214007, K240330, K192147, K181959, K143053, K142782, K141712, K140963, K141612, K141071,

	• STERIS V-PRO® 60 (Lumen, Non-Lumen and Flexible Cycles) • STERIS V-PRO® s2 (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) • 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, (ULTRA GI SMART-FOLD only)) • STERILUCENT® HC80TT Sterilization Cycles (Lumen and Flexible Cycles) HALYARD ONE-STEP, QUICK-CHECK, and SEQUENTIAL additionally includes: • Stryker Sterizone VP4 Sterilizer Cycle 1 • Gravity steam (250°F/121°C for 30 minutes) HALYARD SMART-FOLD additionally includes: • STERRAD® 100NX® (ULTRA GI Cycle) • STERRAD® 100NX® with ALLClear® Technology (ULTRA GI Cycle)		K113806, K112805, K112300, K092167, K091685, and K082177.
Maintenance of Package Integrity	1 year, except for gravity steam (30 days), STERRAD ULTRA GI (3 months) and Sterilucent (6 months).	1 year	Similar. The subject device has been validated for additional cycles, while the predicate has been validated for Stryker Sterizone VP4 Cycle 1.
Technology	Tortuous sheet material used to enclose medical devices that are to be sterilized by a healthcare	Tortuous sheet material used to enclose medical devices that are to be sterilized by a healthcare	Same

	provider to allow sterilization of the enclosed medical device(s) and maintain sterility of the enclosed device(s) until used	provider to allow sterilization of the enclosed medical device(s) and maintain sterility of the enclosed device(s) until used	
Device Design	HALYARD ONE-STEP and QUICK CHECK Two sheets of nonwoven polypropylene fabric. Each sheet is composed of three thermally-bonded layers consisting of a meltblown polypropylene layer surrounded by spunbond polypropylene layers (SMS)	Two sheets of nonwoven polypropylene fabric. Each sheet is composed of three thermally-bonded layers consisting of a meltblown polypropylene layer surrounded by spunbond polypropylene layers (SMS)	Similar. The HALYARD ONE-STEP and, QUICK CHECK wraps are physically identical to the predicate ONE-STEP and QUICK-CHECK wraps.
	HALYARD SEQUENTIAL A sheet of nonwoven polypropylene fabric composed of three thermally-bonded layers consisting of a meltblown polypropylene layer surrounded by spunbond polypropylene layers (SMS)		
	HALYARD SMART-FOLD Two pre-shaped sheets of Halyard Sterilization Wrap, which include reinforcement zones, medical device placement reference line, a white inner layer, side-tabs with closure strips and pull-tabs to allow convenient wrapping with two sheets simultaneously		
Method for Bonding SMS Layers	Thermal bonding with round pin, hexagonal, triangle bond pattern ("daisy" pattern)	Thermal bonding with round pin, hexagonal, triangle bond pattern ("daisy" pattern)	Same. The devices are physically identical.
Materials	Polypropylene with blue and white pigments	Polypropylene with blue and white pigments	Same. The devices are physically identical.
Distribution	Non-Sterile and Over-the-Counter	Non-Sterile and Over-the-Counter	Same
Single Use Device	Yes	Yes	Same

Summary of Performance Testing

Performance Testing (Bench): Performance testing of HALYARD ONE-STEP, QUICK CHECK, SEQUENTIAL and SMART-FOLD Sterilization Wrap was evaluated and the results showed that acceptance criteria were met demonstrating that the HALYARD ONE-STEP, QUICK CHECK, SEQUENTIAL and SMART-FOLD Sterilization Wrap allows sterilization of its contents using the Steris V-PRO Low Temperature Sterilization system and that sterility is maintained for the testing period of 12 months.

Purpose	Test	Acceptance Criteria	Results
Sterilant Penetration/Efficacy	ANSI/AAMI ST79 ANSI/AAMI/ISO 11138-7	Achieving a 10^{-6} sterility assurance level following processing in a worst-case half-cycle	Passed
Performance Testing (Non-sterile and Sterile)	ANSI/AAMI/ISO 11607-1 Annex B ISO 13938-2 ASTM D4966-12 CPSC 1610	Complies with the selected physical properties	Passed
Maintenance of Package Integrity	ANSI/AAMI/ISO 11607-1 ANSI/AAMI ST79	Maintain sterility for 1 year, except for gravity steam (30 days), STERRAD ULTRA GI (3 months) and Sterilucent (6 months).	Passed
Biocompatibility	ISO 10993-1 ISO 10993-5 ISO 10993-10 ISO 10993-7	Non-cytotoxic Non-irritating Non-sensitizing	Passed
Residuals	Steris V-PRO Low Temperature Sterilization System H_2O_2 residuals Sterizone VP4 Cycle 1 residual H_2O_2 ISO 14937 (ULTRA GI Cycle only) ISO 10993-7 EtO and ECH	$H_2O_2 \leq 0.000218$ mg/cm^2 $H_2O_2 \leq 0.56$ µg/cm^2 $H_2O_2 \leq 9100$ µg/cm^2 EO < 4 mg, ECH < 9 mg	Passed

Performance Testing (Clinical): Clinical evaluations were not required and therefore are not submitted with this 510(k).

Discussion: The HALYARD ONE-STEP, QUICK CHECK, SEQUENTIAL and SMART-FOLD Sterilization Wrap in this submission and the predicate device submission are intended to enclose another medical device that is to be sterilized by a healthcare provider, to allow sterilization of the enclosed medical device(s) and to maintain sterility of the enclosed device(s). The ONE-STEP, QUICK CHECK, SEQUENTIAL and SMART-FOLD Sterilization Wrap in this submission and the predicate device submission have identical intended use, design, materials, specifications, and composition, and are manufactured using identical production methods. The different technological characteristics, that is, the Indication For Use and the Sterilization Parameters, do not affect the performance of the device as evidenced by the results of the nonclinical testing.

Overall Performance Conclusions: The conclusions drawn from the nonclinical tests demonstrate that the subject device in K234050, the HALYARD ONE-STEP, QUICK CHECK, SEQUENTIAL and SMART-FOLD Sterilization Wrap, is as safe, as effective and performs as well as or better than the legally marketed predicate cleared in K214007.