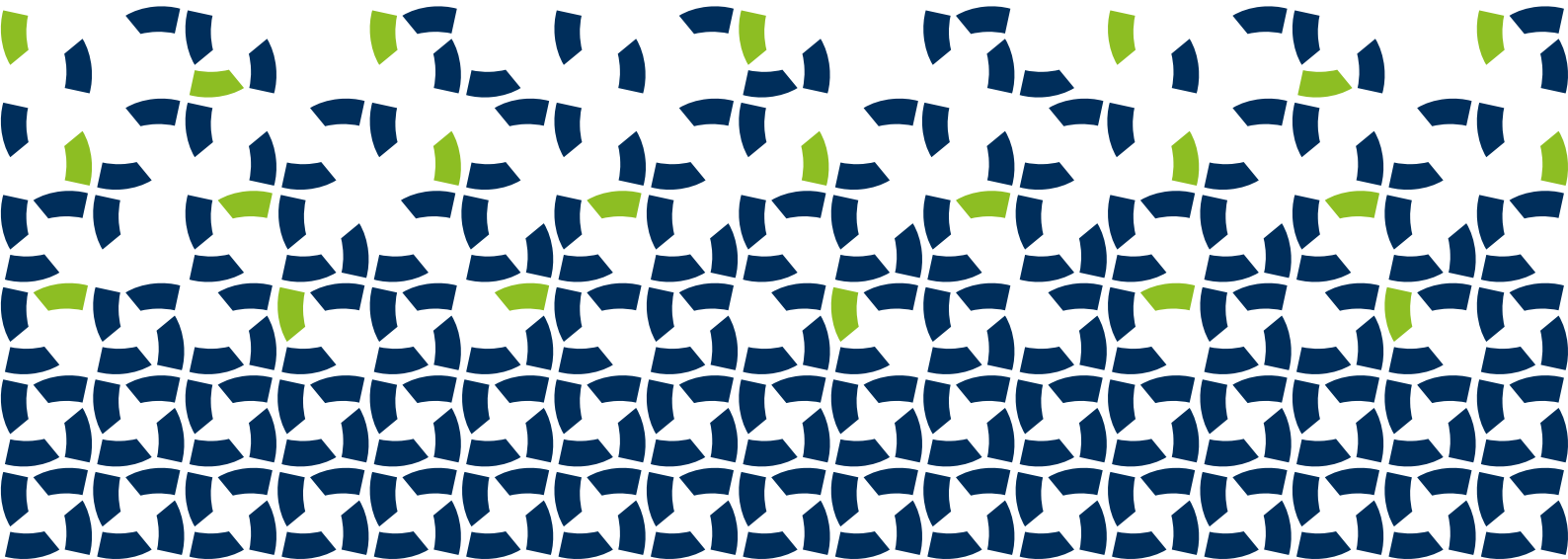
Owens & Minor® | HALYARD

STERILISATION WRAP

COMPLIANCE TO EN ISO 11607-1:2020

Packaging for terminally sterilised medical devices. Requirements for materials, sterile barrier systems and packaging systems



The manufacturer, Owens & Minor Halyard, does not accept any responsibility for the incorrect choice or misuse of the product shown in this brochure. All information contained in this brochure is as accurate as possible at the time of publication, however legislation and regulations are under constant review and may change in the lifetime of this brochure. Accordingly, the specification for the product may be subject to change. Results shown for HALYARD ONE-STEP*[1] are also applicable for QUICK CHECK*

[1] Product availability may vary according to the location

TABLE OF CONTENTS
(NUMBERING FOLLOWS THE ORDER OF EN ISO 11607-1:2020)

HALYARD* STERILISATION WRAP
LIST OF USED ACRONYMS AND ABBREVIATIONS

°C :	Degree Celsius
AAMI :	Association for the Advancement of Medical Instrumentation
AATCC :	American Association of Textile Chemists and Colorists
ANSI :	American National Standards Institute
ASP :	Advanced Sterilisation Products
ASTM :	American Society for Testing and Materials
AVG BW :	Average Basis Weight
BFE :	Bacterial Filtration Efficiency
BI :	Biological Indicator
CD tear :	Cross Direction
cfm :	Cubic feet per minute
CFU :	Colony Forming Units
cm^2 :	Square centimetre
CV :	Coefficient of Variation
DIN :	Deutsches Institut für Normung
ECH :	Ethylene Chlorohydrin
EN :	European Norm
EO :	Ethylene Oxide
F :	Fahrenheit
FIFO :	First In First Out
FTMS :	Flexible Test and Measurement System
in^2 :	Square inches
INDA :	International Nonwovens and Disposables Association
ISO :	International Organization for Standardization
IST :	International Standard Test
kg :	Kilogram
kN:	Kilonewton
l :	Litre
lbs :	Pounds
LPS :	Laser Particle Counter
m^2 :	Square metre
mbar :	Millibar
MD tear :	Machine Direction
mg :	Milligram
ml :	Millilitres
mm :	Millimetre
µM :	Micrometre
MPI :	Maintenance of package integrity
NFPA :	National Fire Prevention Association
osy :	Ounces per square yard
pH :	Measure of the acidity or alkalinity
ppm :	Part per million
PVC :	Polyvinyl chloride
RH :	Relative Humidity
SAL :	Sterility Assurance Level
SBS :	Sterile Barrier System
sec :	Seconds
SOPs :	Standard Operating Procedures
STD :	Standard Deviation
TC :	Technical Committee
TNO :	Netherlands Organization for Applied Scientific Research
UV :	Ultraviolet

HALYARD* STERILISATION WRAP
COMPLIANCE TO EN ISO 11607-1:2020

INTRODUCTION

Dear Customer,

In 2020, the technical committee ISO/TC 198 (Sterilisation of health care products) published an update of EN ISO 11607-1: the 2020 version was a step towards harmonization with the MDR (Medical Device Regulation 2017/745).

An important change with the previous versions of the standard is the evaluation of aseptic presentation. The standard also pays attention the environmental considerations and offers a series of symbols supporting the end-user to distinguish the protective packaging from the Sterile Barrier System.

O&M Halyard always attached a lot of importance to the quality of the bacterial barrier and the compatibility with the various sterilisation methods; hence MPI (Maintenance of Package Integrity) testing has been performed on HALYARD* Sterilisation products. HALYARD* sterilisation packaging material has been tested with a large range of sterilisation modalities (Pre-vacuum steam, Gravity steam, Ethylene Oxide (EO), and Hydrogen Peroxide). All data are valid for HALYARD* QUICK CHECK*, HALYARD QUICK CHECK INTERLEAVED* and SMART-FOLD* Sterilisation Wraps.

This document should answer most of your questions. However, if you do have additional questions, please contact your local O&M Halyard Sales Representative.

This document lists each requirement of EN ISO 11607-1, which is followed by compliance explanation for the relevant clause. The numbering is done according to the EN ISO 11607-1 clauses.

This brochure does not intend to reproduce EN ISO 11607 and has been developed for OUS only: full information around ISO-norms can be consulted on: **https://www.iso.org**

4. GENERAL REQUIREMENTS

4.1 Quality systems

The activities described within this document shall be carried out within a formal quality system.

HALYARD* Sterilisation products are manufactured in our US facility and converted in US and China. These facilities are certified by the following documents:

See Appendix 1: ISO 13485 certificate

4.3 Sampling

The sampling plans used for testing of materials, sterile barrier systems or packaging systems shall be applicable to materials, sterile barrier systems or packaging system being evaluated. Sampling plans shall be based upon statistically valid rationale.

All testing relative to compliance to EN ISO 11607-1 was conducted on product randomly selected from distribution and thus representative of normal variations.

4.4 Test methods

4.4.4 The test method validation shall demonstrate the suitability of the method as used. The following elements shall be included:

- Determination of test method repeatability
- Determination of test method reproducibility
- Establishment of test method sensitivity for integrity tests

Unless otherwise specified in the test methods, test samples shall be conditioned at (23 ± 1)°C and (50 ± 2)% relative humidity for a minimum of 24 h.

Test method	Test
ISO 6588-2/ASTM D2244	Colour leach
ISO 536/ASTM D3776	Grammage
ISO 9073-10/WSP 160-1	Linting
ISO 1974/ASTM D1922	MD Tear
ISO 1974/ASTM D1922	CD Tear
ISO 2758	Bursting Strength (dry)
ISO 3689	Bursting Strength (wet)
EN ISO 1924-2/ ASTM D5034	Elongation (MD)
EN ISO 1924-2/ ASTM D5034	Elongation (CD)
ISO 1924-2/ASTM D5034	MD Tensile Strength (dry)

Test method	Test
ISO 1924-2/ ASTM D5034	CD Tensile Strength (dry)
ISO 3781/ ASTM D2101	MD Tensile Strength (wet)
ISO 3781/ASTM D2101	CD Tensile Strength (wet)
ISO 6588-2	pH
ISO 9197	Sodium Chloride content
ISO 9198	Sodium Sulphate content
DIN 58953-6:2010	Fluorescence
ISO 811/AATCC 127	Hydrostatic Head Pressure
EN 14683/ASTM F2101	Bacterial Filtration Efficiency
EN ISO 11737-1	Microbial Cleanliness

This information is documented in our Design Control system and in specific test methods.

4.5. Documentation

4.5.1. Demonstration of conformity with the requirements of this document shall be recorded

4.5.2. All records shall be retained for a specific period of time. The retention period shall consider factors such as applicable requirements, expiry date and traceability of the medical device or sterile barrier system.

The O&M Halyard Corporate Records Retention procedures are followed, which currently state a lot and batch record retention period of 10 years from the production date.

5. MATERIALS, PREFORMED STERILE BARRIER SYSTEMS AND STERILE BARRIER SYSTEMS

5.1 General requirements

5.1.3 The conditions under which the material and/or preformed sterile barrier system are produced and handled shall be established, controlled and recorded if applicable, in order to ensure the following:

a) The conditions are compatible with the use for which the material and/or sterile barrier system are designed

b) The performance characteristics of the material and/or sterile barrier system are maintained

c) The material and/ or sterile barrier meets the specification

5.1.4 As applicable, the influences of the following shall be evaluated and recorded:

a) Temperature range
A temperature of 143°C should not be exceeded during sterilisation. When utilizing a 100% ethylene oxide (EO) sterilisation cycle with a concentration of 725-735 mg/L at 55°C (131°F) and 40% - 80% relative humidity for 60 minutes with the HALYARD* wrap.
Refer to ANSI/ASHRAE/ASHE Standard 170 Inpatient reference Table 7.1 and Outpatient reference Table 8.1 Recommendations as it relates to facilities temperature and relative humidity in common spaces.

b) Pressure range
HALYARD* Sterilisation Wrap is not impacted by variations in pressure differences during normal conditions of use.

c) Humidity range
EO sterilisation should be performed at 40% - 80% relative humidity.

d) Maximum rate of change of the above, where necessary
HALYARD* Sterilisation Wrap is not impacted by changes in temperature, pressure or humidity during normal conditions of use.

e) Exposure to sunlight or UV light
HALYARD* Sterilisation Wrap is not to be exposed to sunlight or UV light.

f) Cleanliness
No significant amount of particulate matter or linting was observed during normal use.

See paragraph 5.1.7.d.

g) Bioburden
During the whole manufacturing process, environmental conditions are controlled, and bioburden is monitored. As the sterilant penetration and post-sterilisation shelf-life studies were successfully completed on random lots of wrap, it was proven that existing bioburden levels on the wrap are not an issue for sterilisation.

See Appendix 2: Bioburden certificate dated January 2023

h) Electrostatic conductivity
HALYARD* Sterilisation Wrap is treated with less than 0.009% by weight of a potassium phosphate anti-static treatment.

5.1.5 The source, history and traceability of all materials, especially recycled materials, shall be known and controlled to ensure that the preformed sterile barrier system and/or sterile barrier system will consistently meet the requirements of this document.

The source, history and traceability of all materials are controlled by the internal quality systems.

5.1.6 The following properties shall be evaluated:

a) Microbial barrier (see section 5.2)
The microbial barrier properties of the HALYARD* Sterilisation Wrap is validated using the Final Pack Method and Bacterial Filtration Efficiency test methods.

All test results were conditioned at 23°C and 50% RH. The BFE method calls for different conditioning parameters, so the parameters specified in the method were used. All other tests were conditioned per the requirements of the specific method.

Maintenance of Package Integrity (MPI) tests have been performed on the HALYARD* Sterilisation Wrap to demonstrate the microbial barrier properties remain stable during handling, distribution, transport and storage.

See Appendix 3: Physical Properties
See Appendix 15: Final Pack Test Method
See Appendix 16: Whole Package Microbial Challenge Test for HALYARD* Sterilisation Wrap

b) Biocompatibility and toxicological attributes
HALYARD* Sequential and QUICK CHECK* and SMART-FOLD* Sterilisation Wrap products have been evaluated for biocompatibility. Test samples from final finished sterilised (ethylene oxide, gravity steam, pre-vacuum steam) wrap material were evaluated for *in vitro* cytotoxicity, *in vivo* dermal irritation, and dermal sensitization potential. Results from these studies were acceptable and did not show any sign of toxicity. Additional human subject and *in vitro* studies support these results.

When used as directed, Sequential and QUICK CHECK* and SMART-FOLD* Sterilisation Wrap products have a wide margin-of-safety for users or patients and can be considered essentially non-toxic. This statement is based on the assessment of the safety profiles of raw materials used to manufacture all Sterilisation Wrap products in combination with analytical and flammability results and the lack of observed adverse effects in the biocompatibility testing battery conducted with samples of finished product sterilised under ethylene oxide, pre-vacuum steam or gravity steam conditions.

c) Physical and chemical properties
All physical and chemical properties referenced in Appendices 3 and 4 are included in EN 868-2:2017.

See Appendix 3: Physical properties
See Appendix 4: Chemical properties

d) Compatibility with respect to forming and sealing processes
HALYARD* Sterilisation Wrap with KIMGUARD* fabric technology has been used for over 20 years and has demonstrated to have excellent drapability that conforms to equipment pack contours smoothly and closely.

e) Compatibility with respect to the intended sterilisation process(es) (see section 5.3)
The physical properties of the wrap were tested both pre-sterilisation and post-sterilisation with steam, ethylene oxide, formaldehyde and gas plasma sterilisation and the design specifications were met in all cases.

See Appendix 7: Pre-Vacuum Steam Sterilant Penetration Study Results for HALYARD* Sequential and ONE-STEP* Sterilisation Wrap
See Appendix 8: Sterrad® Sterilisation MPI Study Results for HALYARD ONE-STEP* and QUICK-CHECK* Sterilisation Wraps
See Appendix 9: Amsco V-Pro Sterilisation MPI Study Results of HALYARD ONE-STEP* Sterilisation Wrap
See Appendix 10: Sterilucent Sterilisation Compatibility and MPI Study Results for HALYARD ONE-STEP* Sterilisation Wrap
See Appendix 11: Ethylene Oxide Sterilant Penetration and Residuals Study Results for HALYARD* Sequential and ONE-STEP* Sterilisation Wrap
See Appendix 12: Formaldehyde Sterilisation Compatibility and Residuals Study Results for HALYARD* Sequential and ONE-STEP* Sterilisation Wrap

f) Any use by date limitations for pre-sterilisation storage and shelf-life limitations for post-sterilisation storage
Healthcare facilities may use established event- and/or time-related protocols to monitor sterility maintenance of packages wrapped with the Sequential, QUICK CHECK* or SMART-FOLD* Sterilisation Wraps in accordance with accepted standards of practice. Real-time testing simulating clinical use supports maintenance of package sterility for 1 year; however, this time-point does not prevent facilities from continuing to use established healthcare facility protocols.

The pre-sterilisation shelf life of HALYARD* Sterilisation Wrap products is 5 years.

5.1.7 Materials, e.g. wrapping materials, paper, plastic film, nonwovens or reusable fabrics, shall meet the following general performance requirements.

a) Materials shall be non-leaching and odorless under specified conditions of use, to such an extent that neither performance nor safety is impaired and the medical devices with which they are in contact are not adversely affected.
HALYARD* Sterilisation Wrap does not show any color leach as tested with ISO 6588-2, hot extraction method. HALYARD* Sterilisation Wrap is odorless under normal conditions of use.

See Appendix 4: Chemical properties

b) Materials shall be free of holes, cracks, tears, creases or localized thickening and/or thinning sufficient to impair functioning.
The manufacturing facilities use standard operating procedures (SOPs) to routinely inspect for holes and other visual issues and to correct any issues that may arise, with the goal that customers receive product that is free of defects that could impair the wrap's intended use. Additionally, users are instructed to examine the wrap prior to use and to discard if damage or extraneous matter is detected.

c) Materials shall have a basis weight (mass per unit area) which is consistent with the specified value.
The HALYARD* Sterilisation Wrap does not show significant variations in basis weight. Grammage was determined based on ISO 536.

See Appendix 6: Basis Weight of Materials Not Requiring Conditioning

d) Materials shall exhibit acceptable levels of cleanliness, particulate matter and linting.

HALYARD* Sterilisation Wrap was tested with the Textiles — Test methods for nonwovens — Part 10: Lint and other particles generation in the dry state (ISO-9073-10). The test results show that the level of linting/particulate matter/cleanliness stays well below Halyard internal specifications.

See Appendix 3: Physical properties

e) Materials shall comply with established specific or minimum physical properties, such as tensile strength, thickness variation, tear resistance, air permeance and burst strength.
All types of HALYARD* Sterilisation Wrap comply with the specified physical properties as set out in EN 868-2: 2017.

See Appendix 3: Physical properties

f) Materials shall conform to established specific chemical characteristics (such as pH value, chloride, and sulfate content) to meet the requirements of the medical device, packaging system or sterilisation process.
All types of HALYARD* Sterilisation Wrap comply with the specified chemical characteristics as set out in EN 868-2: 2017.

See Appendix 4: Chemical properties

g) Materials shall not contain or release material known to be toxic in sufficient quantity to cause a health hazard either before, during or after sterilisation under the conditions of use.
The wrap material is composed of polypropylene with the addition of less than 2% by weight of phthalocyanine blue pigment, less than 1% by weight of titanium dioxide pigment, and less than 0.009% by weight of a potassium phosphate anti-static treatment.

HALYARD* Sterilisation Wrap products have been evaluated for biocompatibility. Test samples from final finished sterilised (ethylene oxide, gravity steam, and pre-vacuum steam) wrap material were evaluated for *in vitro* cytotoxicity, *in vivo* dermal irritation, and dermal sensitization potential. Results from these studies were acceptable and did not show any sign of toxicity. Additional human subject and *in vitro* studies support these results.

See section 5.1.6.b

h) Materials shall have microbial barrier properties which are consistent with the specified acceptance criteria unless they meet the criterion of impermeability when evaluated as per Annex C.

The microbial barrier properties of HALYARD* Sterilisation Wrap products has been determined using the standard EN 14683 - annex B (2019) + AC (2019), which is comparable to Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus (ASTM F2101) and Standard Test Method For Microbial Ranking Of Porous Packaging Materials (Exposure Chamber Method) (ASTM F1608). The material is validated using a risk-based approach, where statistical sampling takes place to assure that the wrapping material meets the microbial barrier properties against acceptance criteria within Product Requirement Specifications (PRS).

5.1.8 In addition to the requirements given in 5.1.1 through 5.1.7, adhesive-coated materials shall meet the requirements listed below.

a) Coating patterns shall be continuous without skips or breaks in the pattern sufficient to cause a discontinuity in the seal.
Not Applicable

b) Materials shall demonstrate minimum specified seal strength when a seal is formed with another specified material under specified conditions.
Not Applicable

c) Materials shall demonstrate minimum specified seal strength when a seal is formed with another specified material under specified conditions
Not Applicable

5.1.9 In addition to the requirements given in 5.1.1 through 5.1.7 and, if appropriate, 5.1.8, sterile barrier systems and pre-formed sterile barrier systems shall meet the requirements listed below.

a) Sterile barrier systems and preformed sterile barrier systems shall meet the requirements of ISO 11607-2.
Not Applicable

b) Materials and components, e.g. coatings, ink or chemical indicators, shall not adversely affect the medical device by reaction, contamination and/or transfer before, during or after the defined sterilisation process.
There was no change in the colorfastness of the ink caused by the sterilisation cycles.

See Appendix 5: Executive Summary Colorfastness Study for HALYARD ONE-STEP* Sterilisation Wrap

c) If formed by sealing, the specified requirements for seal width and seal strength shall be met.
Not applicable.

d) Peel-open characteristics shall be continuous and homogeneous, without delamination or tearing of the material that can affect aseptic opening and presentation.
Not applicable.

e) Once formed, the sterile barrier system shall provide seal integrity and/or closure integrity until it is opened at the point of use.
The method of wrapping provides a tortuous path, which is a barrier to microorganisms. This was demonstrated via maintenance of package integrity testing and the final pack test developed by TNO.

During MPI-testing the packages are sterilised with the desired sterilisation modality. Following sterilisation and cooling or aeration, a designated number of packages (negative controls) are immediately tested for sterility to assure steriliser efficacy. Both the biological indicators and the gauze stacks from the negative controls are cultured to assure steriliser efficacy. Additional control packs of each wrap type are utilised to verify that the contamination can be detected, to ensure that wet packs (for pre-vacuum steam sterilisation) are not a source of contamination in the study, and to monitor bioburden levels throughout the study.

After sterilisation and cooling or aeration, the test packages are removed from the steriliser, they undergo a series of handling and transport events, where once a week each pack is rotated 180° and relocated to a different shelf within the facility. For the duration of the study, the packs are stored under controlled conditions simulating a hospital sterile storage environment. After 30 days, 6 months and/or 1 year of storage, representative sterilised packages are tested for sterility.

See Appendix 8: Sterrad® Sterilisation MPI Study Results for HALYARD ONE-STEP* and QUICK-CHECK* Sterilisation Wraps
See Appendix 9: Amsco V-PRO Sterilisation MPI Study Results of HALYARD ONE-STEP* Sterilisation Wrap
See Appendix 10: Sterilucent Sterilisation Compatibility and MPI Study Results for HALYARD ONE-STEP* Sterilisation Wrap
See Appendix 13: EO and Pre-vacuum Steam Sterilisation MPI Study Results for HALYARD* Sequential and ONE-STEP* Sterilisation Wrap
See Appendix 15: Final Pack Test Method for HALYARD ONE-STEP* Sterilisation Wrap Using the Prion Cycle (18 minutes)
See Appendix 16: Whole Package Microbial Challenge Test for HALYARD* Sterilisation Wrap

f) Opening a seal or closure should be irreversible or destructive. If the open seal or closure is reversible, it shall be clearly evident that the seal or closure has been opened.
HALYARD* Sterilisation Wrap is closed using tape or indicator tape: the tape forms the seal until the package is opened. Once a package is opened, the torn tape clearly indicates that the package has been opened and cannot be closed again.

5.2 Microbial barrier properties

5.2.1 If not declared porous material, the impermeability shall be determined in accordance with Annex C.

HALYARD* Sterilisation Wrap is not impermeable. However, it has demonstrated excellent microbial barrier properties.

5.2.2 A demonstration that the material is impermeable shall satisfy the microbial barrier requirements.

HALYARD* Sterilisation Wrap is not impermeable, however BFE testing has demonstrated excellent microbial barrier properties.

See Appendix 3: Physical Properties.

5.2.3 Porous materials shall provide an adequate microbial barrier to microorganisms.

HALYARD* Sterilisation Wrap shows excellent microbial barrier properties as demonstrated in the Final Pack Test and bacterial filtration efficiency test performed as per EN 14683.

See Appendix 3: Physical properties
See Appendix 15: Final Pack Test Method
See Appendix 16: Whole Package Microbial Challenge Test for HALYARD* Sterilisation Wrap

5.3 Compatibility with the sterilisation process

5.3.1 It shall be demonstrated that the materials and preformed sterile barrier system, and sterile barrier systems are suitable for use in the specified sterilisation process(es), cycle parameters and process limits.

The HALYARD* Sterilisation Wrap has successfully passed the sterilant penetration tests for Steam, Ethylene Oxide, Formaldehyde and Hydrogen Peroxide Gas Plasma sterilisation.

See paragraph 5.1.6 e.

5.3.2 Determination of suitability for the intended purpose shall include consideration of material variations that will occur.

Suitability has been examined by using different test loads according to the strength of the material that was tested and mimicking the content of real-world instrument trays.

All testing was conducted on products randomly selected from distribution and thus representative of normal variations.

5.3.3 The performance of the materials shall be evaluated to ensure that the material performance remains within specified limits after exposure to all the specified sterilisation processes.

HALYARD* Sterilisation Wrap was tested and met specifications for strength, barrier and lint both before and after sterilisation by pre-vacuum steam at 132°C (270°F) for 4 minutes with a 20-minute dry time and at 135°C for 30 minutes or by ethylene oxide (100% EO with a concentration of 725 mg/L at 54-55°C and 40% - 80% relative humidity for 60 minutes and subsequent aeration).

See section 5.1.7 e.

5.4 Labelling system

The labelling system shall

a) remain intact and legible until the point of use

b) be compatible with the materials, sterile barrier system and medical device during and after the specified sterilisation process(es) and cycle parameters and shall not adversely affect the sterilisation process, and

c) not be printed or written in ink of a type which can be transferred to the medical device nor react with the packaging material and/or system to impair the utility of the packaging material and/or system, nor change color to an extent which renders the label illegible.

HALYARD* Sterilisation Wrap is compatible with most sterilisation closure tapes. Writing should not be applied directly on the wrap.

See Appendix 5: Executive Summary Colorfastness Study for HALYARD ONE-STEP* Sterilisation Wrap

5.5 Storage and transport

Materials and preformed sterile barrier systems shall be transported and stored under conditions that ensure that the performance characteristics remain with the specified limits.

NOTE: This can be accomplished by:

a) demonstrating retention of these characteristics under defined storage conditions.

b) ensuring that storage conditions remain within specified limits.

The wraps are packaged in plastic shrink wrap (to maintain wrap cleanliness) for general debris protection and then packed into a corrugated shipper composed of natural kraft (to protect from ultraviolet light and damage during shipping/transport). A chipboard sheet is be placed on top of the product before closing and sealing the case to protect product from damage per end-user opening product.

The transport packaging mentions the following information as per EN 868-2:2017:

a) reference number

b) quantity

c) manufacturer name and product name

d) date of manufacture

e) lot number

f) nominal sheet size in centimeters

g) the recommended storage conditions

General Storage recommendation for HALYARD* Sterilisation Wrap prior & post sterilisation are:

- The location should be
  - clean
  - dust-free
  - away from fluorescent or ultraviolet light
- Use first in, first out (FIFO) stock rotation.

7. USABILITY EVALUATION FOR ASEPTIC PRESENTATION

7.1

A documented usability evaluation shall be conducted to demonstrate that the sterile contents can be aseptically removed from the sterile barrier system for presentation.

The usability evaluation for aseptic presentation for HALYARD* Sterilisation Wrap indicates that the sterile contents can be aseptically removed from sterile barrier system. The information is documented in our Design Control system.

7.2

The usability evaluation for aseptic presentation shall include an assessment of

a) the ability to identify where to begin opening,

b) the ability to recognize and perform the technique required to open the sterile barrier system without contaminating or damaging the contents, and

c) the ability to subsequently present the contents aseptically.

The usability evaluation for aseptic presentation for HALYARD* Sterilisation Wrap demonstrates the ability to identify where to begin opening of the sterile barrier system, the ability to recognize and perform the technique required to open the sterile barrier system without contaminating or damaging the contents, and the ability to subsequently present the contents aseptically. The information is documented in our Design Control system.

7.3

The evaluation may be done under real or simulated conditions of use.

The usability evaluation for aseptic presentation for HALYARD* Sterilisation Wrap was conducted under real conditions.

7.4

Usability evaluations may be leveraged between sterile product families and packaging families based on worst-case considerations or other valid rationales.

7.5

If the usability evaluation does not meet the three steps in 7.2, then either the sterile barrier system may be redesigned and/or additional information provided to the user. The ability to successfully open and present the contents shall then be evaluated in a subsequent usability evaluation.

The usability evaluation for aseptic presentation for HALYARD* Sterilisation Wraps meets all requirements in 7.2. HALYARD* Sterilisation Wrap usability study demonstrated the ability to successfully open the sterile barrier system without contaminating or damaging the contents, and the ability to subsequently present the contents aseptically.

See Appendix 14: Aseptic Opening Study for QUICK CHECK* Sterilisation Wrap.

bsi.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

O & M Halyard, Inc.
9120 Lockwood Blvd
Mechanicsville
Virginia
23116
USA

Holds Certificate Number: FM 697013

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

The design and development, manufacture and distribution of surgical gowns, protective garments, face masks, surgical drapes, orthopedic soft goods, patient care products, cold therapy products, C-Section packs, OB Packs, orthopedic packs, sterile and non-sterile medical examination gloves, Temperature management systems for the areas of general surgery and general medical use and sterilization wrap and non-woven materials for medical devices.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2014-12-09
Effective Date: 2023-01-09
Latest Revision Date: 2023-01-07
Expiry Date: 2026-01-08

...making excellence a habit.™

APPENDIX 1: ISO 13485:2016 CERTIFICATE

Certificate No: FM 697013

Location	Registered Activities
O & M Halyard, Inc. 9120 Lockwood Blvd Mechanicsville Virginia 23116 USA	Headquarter management activities.
O & M Halyard, Inc. 1 Edison Drive Alpharetta Georgia 30005 USA	The design and development of surgical gowns, protective garments, face masks, surgical drapes, orthopedic soft goods, patient care products, cold therapy products, C-Section packs, OB Packs, orthopedic packs, sterile and non-sterile medical examination gloves, Temperature management systems for the areas of general surgery and general medical use and sterilization wrap and non-woven materials for medical devices.
Halyard North Carolina, LLC 389 Clyde Fitzgerald Rd. Linwood North Carolina 27299 USA	The manufacture of nonwoven materials for medical devices, Sterilization wrap, non-sterile face masks (respirators), and infection control products including disposable gowns and linens.
La Ada de Acuna 14 Finegan Road Del Rio Texas 78840 USA	Receiving and Incoming Inspection, Warehouse and Distribution. The manufacture of non-sterile face masks and respirators.
O&M Halyard Honduras S.A. de C.V. Carretera Tegucigalpa Villanueva Cortes Honduras	The manufacture and distribution of disposable sterile and non-sterile surgical gowns.
La Ada de Acuna Avenida Hidalgo #16 Parque Industrial San Carlos Nogales Sonora 84092 Mexico	Receiving and incoming inspection. Manufacturer/Conversion of nonwoven materials.

Original Registration Date: 2014-12-09
Effective Date: 2023-01-09
Latest Revision Date: 2023-01-07
Expiry Date: 2026-01-08

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APPENDIX 1: ISO 13485:2016 CERTIFICATE

Certificate No: FM 697013

Location	Registered Activities
La Ada de Acuna Km. 4.5 Carretera Presa La Amistad Ciudad De Acuna Coahuila 26220 Mexico	The manufacture of non-sterile face masks (surgical isolation, industrial and respirator), non-surgical gowns, cold therapy products, and sterilization wrap.
La Ada de Acuna S.De. R.L. De C.V AV. Hidalgo #6 Esq., Blvd., Luis Donaldo Colosio, Col. Educativa Nogales Sonora Sonora 84093 Mexico	The manufacture of disposable products including sterile and non sterile surgical packs, gowns and components. The manufacture of temperature management systems for areas of general surgery.
Safeskin Medical & Scientific (Thailand) Ltd. 200 Moo 8, Kanchanavanich Road, Tambol Prik, Amphur Sadao, Songkhla 90120 Thailand	The design and development, production and distribution of industrial gloves, sterile and non-sterile medical examination gloves.
La Ada de Acuna II Lote #8 del parque Industrial la Paz II Carretera Santa Eulalia #810 Cd. Acuña Coahuila C.P.26238 Mexico	Warehouse space for the storage of raw materials, components, and spare parts.
O&M Halyard Honduras S.A. de C.V. Carreterra Tegucigalpa Villanueva Building #7 Cortes Honduras	The manufacture and distribution of disposable non-sterile apparel and surgical gowns.

Original Registration Date: 2014-12-09
Latest Revision Date: 2023-01-07

Effective Date: 2023-01-09
Expiry Date: 2026-01-08

Page: 3 of 3

APPENDIX 2: BIOBURDEN CERTIFICATE

O&M HALYARD produces Sterilisation Wrap products that are monitored for microbial cleanliness levels. The product(s) is tested according to requirements of EN ISO 11737-1:2018 Sterilisation of health care products – Microbiological methods – Part 1: Determination of a population of microorganisms.

The product meets or exceeds the Cleanliness microbial / Bioburden limits (≤ 300 CFU/100 cm^2) as established in BS EN 13795 – 1:2019 Surgical clothing and drapes. Requirements and test methods — Surgical drapes and gowns, Annex B.2, Table 1 and 2.

References:
Centexbel Summary: 22.04219.03,
RST-74726

APPENDIX 3: PHYSICAL PROPERTIES

Physical Properties Test Methodology and Results for HALYARD QUICK CHECK* H100 Sterilisation Wrap

Test	Methodology	Interpretation of Results	HALYARD QC H100 Sterilisation Wrap Results[1]
BACTERIAL FILTRATION EFFICIENCY	Staphylococcus aureus particles are aerosolized and sprayed onto the fabric. Results are reported as percent efficiency and correlate with the ability of the fabric to resist bacterial penetration.[2,3]	Higher numbers in this test indicate better barrier efficiency.	99.6 %[4]
TENSILE STRENGTH	Force is applied to the test fabric until the fabric breaks. The force required to break the fabric – grab tensile load – is measured. Results are reported as pounds of force required to break the fabric. The lower result of CD or MD direction is reported in lbf and kN/m for both wet and dry standard test.[5]	Higher numbers indicate a stronger fabric.	20.9 lbf; 0.96 kN/m (Dry)[6] 21.9 lbf; 0.96 kN/m (Wet)[6]
RESISTANCE TO LINTING	In a controlled environment, a 8.6"x11.2" (220 mm x 285 mm) sample of fabric is clamped inside a Gelbo Dry Particle Generator. It is then flexed one time every second for a period of five minutes. Particles generated during the test period are counted using a laser particle counter. Results are expressed as the Coefficient of linting (C_L) of lint particles generated greater than 3 microns in size.[7]	Lower numbers in this test indicate less lint, which is desirable in the operating room environment. C_L = Log10 Linting	3.1[6]
HYDROSTATIC PRESSURE	The fabric sample is clamped onto the bottom of a vertical column, into which water is poured. When leakage is observed on the underside of the fabric, the amount of water in the column is measured. Results are expressed in millibar (mbar) of water pressure a fabric can repel before leaking.[8]	A higher number indicates greater resistance to water penetration.	98.1 mbar[6]

1. The above results are averages based upon testing of representative samples selected randomly from distribution. Since HALYARD* SEQUENTIAL* and QUICK CHECK* sterilisation wrap consists of two layers bonded together, all testing was conducted on two layers.
2. Centexbel Laboratories, Inc., Etienne Sabbelaan 49, 8500 Kortrijk, Belgium. "Bacterial Filtration Efficiency."
3. EN 14683 – Annex B (2019) + AC (2019). "Medical face masks – Requirements and test methods".
4. Test data generated by Centexbel Laboratories, Inc., Etienne Sabbelaan 49, 8500 Kortrijk, Belgium. Ref. 18159027
5. ISO 1924-2:2008. "Paper and board – Determination of tensile properties – Part 2: Constant rate of elongation method (20 mm/min)"/ISO 3781:2011. "Paper and board – Determination of tensile strength after immersion in water."
6. Test data generated by Centexbel Laboratories, Inc., Etienne Sabbelaan 49, 8500 Kortrijk, Belgium via request # 74726
7. Standard test ISO 9073-10 (2003) "Textiles – Test methods for nonwovens".
8. ISO 811 (2018). "Textiles – Determination of resistance to water penetration – Hydrostatic pressure test".

Physical Properties Test Methodology and Results for HALYARD QUICK CHECK* H200 Sterilisation Wrap

Test	Methodology	Interpretation of Results	HALYARD QC H200 Sterilisation Wrap Results[1]
BACTERIAL FILTRATION EFFICIENCY	Staphylococcus aureus particles are aerosolized and sprayed onto the fabric. Results are reported as percent efficiency and correlate with the ability of the fabric to resist bacterial penetration.[2,3]	Higher numbers in this test indicate better barrier efficiency	99.8 %[4]
TENSILE STRENGTH	Force is applied to the test fabric until the fabric breaks. The force required to break the fabric – grab tensile load – is measured. Results are reported as pounds of force required to break the fabric. The lower result of CD or MD direction is reported in lbf and kN/m for both wet and dry standard test.[5]	Higher numbers indicate a stronger fabric.	24.6 lbf; 1.08 kN/m (Dry)[6] 24.3 lbf; 1.07 kN/m (Wet)[6]
RESISTANCE TO LINTING	In a controlled environment, a 8.6"x11.2" (220 mm x 285 mm) sample of fabric is clamped inside a Gelbo Dry Particle Generator. It is then flexed one time every second for a period of five minutes. Particles generated during the test period are counted using a laser particle counter. Results are expressed as the Coefficient of linting (C_L) of lint particles generated greater than 3 microns in size.[7]	Lower numbers in this test indicate less lint, which is desirable in the operating room environment. C_L = Log10 Linting	3.1[6]
HYDROSTATIC PRESSURE	The fabric sample is clamped onto the bottom of a vertical column, into which water is poured. When leakage is observed on the underside of the fabric, the amount of water in the column is measured. Results are expressed in millibar (mbar) of water pressure a fabric can repel before leaking.[8]	A higher number indicates greater resistance to water penetration.	98.1 mbar[6]

1. The above results are averages based upon testing of representative samples selected randomly from distribution. Since HALYARD* SEQUENTIAL* and QUICK CHECK* sterilisation wrap consists of two layers bonded together, all testing was conducted on two layers.
2. Centexbel Laboratories, Inc., Etienne Sabbelaan 49, 8500 Kortrijk, Belgium. "Bacterial Filtration Efficiency."
3. EN 14683 – Annex B (2019) + AC (2019). "Medical face masks – Requirements and test methods".
4. Test data generated by Centexbel Laboratories, Inc., Etienne Sabbelaan 49, 8500 Kortrijk, Belgium. Ref. 18159027
5. ISO 1924-2:2008. "Paper and board – Determination of tensile properties – Part 2: Constant rate of elongation method (20 mm/min)"/ISO 3781:2011. "Paper and board – Determination of tensile strength after immersion in water."
6. Test data generated by Centexbel Laboratories, Inc., Etienne Sabbelaan 49, 8500 Kortrijk, Belgium via request # 74726
7. Standard test ISO 9073-10 (2003) "Textiles – Test methods for nonwovens".
8. ISO 811 (2018). "Textiles – Determination of resistance to water penetration – Hydrostatic pressure test".

Physical Properties Test Methodology and Results for HALYARD QUICK CHECK* H300 Sterilisation Wrap

Test	Methodology	Interpretation of Results	HALYARD QC H300 Sterilisation Wrap Results[1]
BACTERIAL FILTRATION EFFICIENCY	Staphylococcus aureus particles are aerosolized and sprayed onto the fabric. Results are reported as percent efficiency and correlate with the ability of the fabric to resist bacterial penetration.[2,3]	Higher numbers in this test indicate better barrier efficiency	99.6 %[4]
TENSILE STRENGTH	Force is applied to the test fabric until the fabric breaks. The force required to break the fabric – grab tensile load – is measured. Results are reported as pounds of force required to break the fabric. The lower result of CD or MD direction is reported in lbf and kN/m for both wet and dry standard test.[5]	Higher numbers indicate a stronger fabric.	45.0 lbf; 1.98 kN/m (Dry)[6] 46.0 lbf; 2.02 kN/m (Wet)[6]
RESISTANCE TO LINTING	In a controlled environment, a 8.6"x11.2" (220 mm x 285 mm) sample of fabric is clamped inside a Gelbo Dry Particle Generator. It is then flexed one time every second for a period of five minutes. Particles generated during the test period are counted using a laser particle counter. Results are expressed as the Coefficient of linting (C_L) of lint particles generated greater than 3 microns in size.[7]	Lower numbers in this test indicate less lint, which is desirable in the operating room environment. C_L = Log10 Linting	2.7[6]
HYDROSTATIC PRESSURE	The fabric sample is clamped onto the bottom of a vertical column, into which water is poured. When leakage is observed on the underside of the fabric, the amount of water in the column is measured. Results are expressed in millibar (mbar) of water pressure a fabric can repel before leaking.[8]	A higher number indicates greater resistance to water penetration.	76.5 mbar[6]

1. The above results are averages based upon testing of representative samples selected randomly from distribution. Since HALYARD* SEQUENTIAL* and QUICK CHECK* sterilisation wrap consists of two layers bonded together, all testing was conducted on two layers.
2. Centexbel Laboratories, Inc., Etienne Sabbelaan 49, 8500 Kortrijk, Belgium. "Bacterial Filtration Efficiency."
3. EN 14683 – Annex B (2019) + AC (2019). "Medical face masks - Requirements and test methods".
4. Test data generated by Centexbel Laboratories, Inc., Etienne Sabbelaan 49, 8500 Kortrijk, Belgium. Ref. 18159027
5. ISO 1924-2:2008. "Paper and board – Determination of tensile properties – Part 2: Constant rate of elongation method (20 mm/min)"/ISO 3781:2011. "Paper and board - Determination of tensile strength after immersion in water."
6. Test data generated by Centexbel Laboratories, Inc., Etienne Sabbelaan 49, 8500 Kortrijk, Belgium via request # 74726
7. Standard test ISO 9073-10 (2003) "Textiles – Test methods for nonwovens".
8. ISO 811 (2018). "Textiles – Determination of resistance to water penetration – Hydrostatic pressure test".

Physical Properties Test Methodology and Results for HALYARD QUICK CHECK* H400 Sterilisation Wrap

Test	Methodology	Interpretation of Results	HALYARD QC H400 Sterilisation Wrap Results[1]
BACTERIAL FILTRATION EFFICIENCY	Staphylococcus aureus particles are aerosolized and sprayed onto the fabric. Results are reported as percent efficiency and correlate with the ability of the fabric to resist bacterial penetration.[2,3]	Higher numbers in this test indicate better barrier efficiency	99.8 %[4]
TENSILE STRENGTH	Force is applied to the test fabric until the fabric breaks. The force required to break the fabric – grab tensile load – is measured. Results are reported as pounds of force required to break the fabric. The lower result of CD or MD direction is reported in lbf and kN/m for both wet and dry standard test.[5]	Higher numbers indicate a stronger fabric.	56.9 lbf; 2.50 kN/m (Dry)[6] 56.8 lbf; 2.50 kN/m (Wet)[6]
RESISTANCE TO LINTING	In a controlled environment, a 8.6"x11.2" (220 mm x 285 mm) sample of fabric is clamped inside a Gelbo Dry Particle Generator. It is then flexed one time every second for a period of five minutes. Particles generated during the test period are counted using a laser particle counter. Results are expressed as the Coefficient of linting (C_L) of lint particles generated greater than 3 microns in size.[7]	Lower numbers in this test indicate less lint, which is desirable in the operating room environment. C_L = Log10 Linting	2.7[6]
HYDROSTATIC PRESSURE	The fabric sample is clamped onto the bottom of a vertical column, into which water is poured. When leakage is observed on the underside of the fabric, the amount of water in the column is measured. Results are expressed in millibar (mbar) of water pressure a fabric can repel before leaking.[8]	A higher number indicates greater resistance to water penetration.	100.0 mbar[6]

1. The above results are averages based upon testing of representative samples selected randomly from distribution. Since HALYARD* SEQUENTIAL* and QUICK CHECK* sterilisation wrap consists of two layers bonded together, all testing was conducted on two layers.
2. Centexbel Laboratories, Inc., Etienne Sabbelaan 49, 8500 Kortrijk, Belgium. "Bacterial Filtration Efficiency."
3. EN 14683 – Annex B (2019) + AC (2019). "Medical face masks – Requirements and test methods".
4. Test data generated by Centexbel Laboratories, Inc., Etienne Sabbelaan 49, 8500 Kortrijk, Belgium. Ref. 18159027
5. ISO 1924-2:2008. "Paper and board – Determination of tensile properties – Part 2: Constant rate of elongation method (20 mm/min)"/ISO 3781:2011. "Paper and board – Determination of tensile strength after immersion in water."
6. Test data generated by Centexbel Laboratories, Inc., Etienne Sabbelaan 49, 8500 Kortrijk, Belgium via request # 74726
7. Standard test ISO 9073-10 (2003) "Textiles – Test methods for nonwovens".
8. ISO 811 (2018). "Textiles – Determination of resistance to water penetration – Hydrostatic pressure test".

Physical Properties Test Methodology and Results for HALYARD QUICK CHECK* H500 Sterilisation Wrap

Test	Methodology	Interpretation of Results	HALYARD QC H500 Sterilisation Wrap Results[1]
BACTERIAL FILTRATION EFFICIENCY	Staphylococcus aureus particles are aerosolized and sprayed onto the fabric. Results are reported as percent efficiency and correlate with the ability of the fabric to resist bacterial penetration.[2,3]	Higher numbers in this test indicate better barrier efficiency	99.9 %[4]
TENSILE STRENGTH	Force is applied to the test fabric until the fabric breaks. The force required to break the fabric – grab tensile load – is measured. Results are reported as pounds of force required to break the fabric. The lower result of CD or MD direction is reported in lbf and kN/m for both wet and dry standard test.[5]	Higher numbers indicate a stronger fabric.	65.0 lbf; 2.86 kN/m (Dry)[6] 67.1 lbf; 2.95 kN/m (Wet)[6]
RESISTANCE TO LINTING	In a controlled environment, a 8.6"x11.2" (220 mm x 285 mm) sample of fabric is clamped inside a Gelbo Dry Particle Generator. It is then flexed one time every second for a period of five minutes. Particles generated during the test period are counted using a laser particle counter. Results are expressed as the Coefficient of linting (C_L) of lint particles generated greater than 3 microns in size.[7]	Lower numbers in this test indicate less lint, which is desirable in the operating room environment. C_L = Log10 Linting	2.7[6]
HYDROSTATIC PRESSURE	The fabric sample is clamped onto the bottom of a vertical column, into which water is poured. When leakage is observed on the underside of the fabric, the amount of water in the column is measured. Results are expressed in millibar (mbar) of water pressure a fabric can repel before leaking.[8]	A higher number indicates greater resistance to water penetration.	91.7 mbar[6]

1. The above results are averages based upon testing of representative samples selected randomly from distribution. Since HALYARD* SEQUENTIAL* and QUICK CHECK* Sterilisation Wrap consists of two layers bonded together, all testing was conducted on two layers.
2. Centexbel Laboratories, Inc., Etienne Sabbelaan 49, 8500 Kortrijk, Belgium. "Bacterial Filtration Efficiency."
3. EN 14683 – Annex B (2019) + AC (2019). "Medical face masks – Requirements and test methods".
4. Test data generated by Centexbel Laboratories, Inc., Etienne Sabbelaan 49, 8500 Kortrijk, Belgium. Ref. 18159027
5. ISO 1924-2:2008. "Paper and board – Determination of tensile properties — Part 2: Constant rate of elongation method (20 mm/min)"/ISO 3781:2011. "Paper and board – Determination of tensile strength after immersion in water."
6. Test data generated by Centexbel Laboratories, Inc., Etienne Sabbelaan 49, 8500 Kortrijk, Belgium via request # 74726
7. Standard test ISO 9073-10 (2003) "Textiles – Test methods for nonwovens".
8. ISO 811 (2018). "Textiles – Determination of resistance to water penetration – Hydrostatic pressure test".

Physical Properties Test Methodology and Results for HALYARD* SMART-FOLD* H650 Sterilisation Wrap

Test	Methodology	Interpretation of Results	HALYARD SMART-FOLD* H650 Sterilisation Wrap Results[1]
BACTERIAL FILTRATION EFFICIENCY	Staphylococcus aureus particles are aerosolized and sprayed onto the fabric. Results are reported as percent efficiency and correlate with the ability of the fabric to resist bacterial penetration.[2,3]	Higher numbers in this test indicate better barrier efficiency	99.8 %[4]
TENSILE STRENGTH	Force is applied to the test fabric until the fabric breaks. The force required to break the fabric – grab tensile load – is measured. Results are reported as pounds of force required to break the fabric. The lower result of CD or MD direction is reported in lbf and kN/m for both wet and dry standard test.[5]	Higher numbers indicate a stronger fabric.	111.9 lbf; 4.92 kN/m (Dry)[6,9] 116.1 lbf; 5.10 kN/m (Wet)[6,9] 70.7 lbf; 3.11 kN/m (Dry)[6,10] 72.5 lbf; 3.19 kN/m (Wet)[6,10]
RESISTANCE TO LINTING	In a controlled environment, a 8.6"x11.2" (220 mm x 285 mm) sample of fabric is clamped inside a Gelbo Dry Particle Generator. It is then flexed one time every second for a period of five minutes. Particles generated during the test period are counted using a laser particle counter. Results are expressed as the Coefficient of linting (C_L) of lint particles generated greater than 3 microns in size.[7]	Lower numbers in this test indicate less lint, which is desirable in the operating room environment. C_L = Log10 Linting	2.8[6]
HYDROSTATIC PRESSURE	The fabric sample is clamped onto the bottom of a vertical column, into which water is poured. When leakage is observed on the underside of the fabric, the amount of water in the column is measured. Results are expressed in millibar (mbar) of water pressure a fabric can repel before leaking.[8]	A higher number indicates greater resistance to water penetration.	90.9 mbar[6]

1. The above results are averages based upon testing of representative samples selected randomly from distribution. Since HALYARD* SEQUENTIAL* and QUICK CHECK* Sterilisation Wrap consists of two layers bonded together, all testing was conducted on two layers.
2. Centexbel Laboratories, Inc., Etienne Sabbelaan 49, 8500 Kortrijk, Belgium. "Bacterial Filtration Efficiency."
3. EN 14683 – Annex B (2019) + AC (2019). "Medical face masks – Requirements and test methods".
4. Test data generated by Centexbel Laboratories, Inc., Etienne Sabbelaan 49, 8500 Kortrijk, Belgium. Ref. 18159027
5. ISO 1924-2:2008. "Paper and board – Determination of tensile properties – Part 2: Constant rate of elongation method (20 mm/min)"/ISO 3781:2011. "Paper and board – Determination of tensile strength after immersion in water."
6. Test data generated by Centexbel Laboratories, Inc., Etienne Sabbelaan 49, 8500 Kortrijk, Belgium via request # 74726
7. Standard test ISO 9073-10 (2003) "Textiles – Test methods for nonwovens".
8. ISO 811 (2018). "Textiles – Determination of resistance to water penetration – Hydrostatic pressure test".
9. The data represents the tensile strength for reinforcement layer (3-layers of wrap) for the SMART-FOLD* Sterilisation Wrap.
10. The data represents the tensile strength for 2-layer data for the SMART-FOLD* Sterilisation Wrap.

APPENDIX 4: CHEMICAL PROPERTIES

Properties	Specification	HALYARD* QUICK CHECK* H100	HALYARD* QUICK CHECK* H200	HALYARD* QUICK CHECK* H300	HALYARD* QUICK CHECK* H400	HALYARD* QUICK CHECK* H500	HALYARD* SMART-FOLD* H650
NR. OF LAYERS		2	2	2	2	2	2
PH	EN ISO 868-2 ISO 6588-2	6-7	6-7	6-7	6-7	6-7	6-7
COLOUR LEACH	EN ISO 868-2 ISO 6588-2	No Leach	No Leach	No Leach	No Leach	No Leach	No Leach
SODIUM CHLORIDE %	EN ISO 868-2 ISO 9197	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05
SODIUM SULPHATE %	EN ISO 868-2 ISO 9198	<0.25	<0.25	<0.25	<0.25	<0.25	<0.25
FLUORESCENCE	EN ISO 868-2	None	None	None	None	None	None

References:
Centexbel Summary: 22.04219.03, RST-74726
Report Number 22.04219.03

APPENDIX 5: EXECUTIVE SUMMARY COLORFASTNESS STUDY FOR HALYARD ONE-STEP* STERILISATION WRAP

Each model of HALYARD ONE-STEP* (H100-H500) was tested while non-sterile and after sterilisation by pre-vacuum steam and ethylene oxide for colorfastness of the ink used to indicate the model, lot number, and size along one bonded edge.

Integrated Paper Services (Appleton, WI) performed the colorfastness test according to AATCC 8-2007 and evaluated the samples against a gray scale described in the standard. The gray scale ranges from 1-5 with 1 being the lowest amount of ink transfer onto a muslin sheet and 5 being the highest amount of ink transfer. Ten (10) samples were tested for each model and each of the sterilisation methods (including non-sterile). Non-sterile samples for testing were prepared by the materials evaluation department at Halyard Health. Sterile samples were prepared from wraps sterilised at Nelson Labs (Salt Lake City, UT) using one of the following sterilisation cycles:

Sterilisation Method	Sterilisation Parameters
Pre-vacuum steam sterilisation	Exposure: 132°C/270°F for 4 minutes
	Dry time: 20 minutes
Ethylene oxide (EO) sterilisation	Exposure: 100% EO with a concentration of 725 mg/L at 54-55°C and 40% - 80% relative humidity for 60 minutes
	Aeration: 12 hours at 48°C

Average results for each model and sterilisation cycle are as follows:

	Non-sterile	Ethylene Oxide	Pre-vacuum Steam
H100 ONE-STEP*	1-2	1-2	1-2
H200 ONE-STEP*	1-2	1-2	1-2
H300 ONE-STEP*	1-2	1-2	1-2
H400 ONE-STEP*	1-2	1-2	1-2
H500 ONE-STEP*	1-2	1-2	1-2

These values indicate a small amount of ink transfer onto the muslin sheet for the wrap, both pre-sterile and post-sterilisation by pre-vacuum steam and ethylene oxide. There was no change in the colorfastness of the ink caused by the sterilisation cycles. ISO 10993 biocompatibility testing was performed in a separate study on the sterilised wraps with this ink, with no adverse test results.

APPENDIX 6: BASIS WEIGHT OF MATERIALS NOT REQUIRING CONDITIONING

The test samples where 161.29 cm^2 (25 in^2) in size.

	H100 QC	H200 QC	H300 QC	H400 QC	H500 QC	H650 SF
AVG BW G/M^2	71.23	81.50	97.29	124.53	139.22	151.16
STD	0.06	0.44	1.2	2.0	1.3	1.4
% CV	0	1	1	2	1	1

The Basis Weight results are averages based upon testing of representative samples selected randomly from distribution. Since HALYARD* QUICK CHECK* Sterilisation Wrap consists of two layers bonded together, all testing was conducted on two layers. The test samples where 100 cm^2 (15,5 in^2) in size.

APPENDIX 7: PRE-VACUUM STEAM STERILANT PENETRATION STUDY RESULTS FOR HALYARD* SEQUENTIAL AND ONE-STEP* STERILISATION WRAP

Purpose

HALYARD* Sequential and ONE-STEP* Wrap was validated for use with pre-vacuum steam sterilisation to a sterility assurance level (SAL) of 10-6 using the biological indicator (BI) overkill method.

Test Samples

AAMI challenge test packs were assembled per AAMI ST79 section 10.7.2.1. Each test pack contained sixteen approximately 16 x 26 inch (40.6 x 66.cm) cotton surgical towels, two biological indicators and two chemical integrators. The contents of each package wrapped with ONE-STEP* Sterilisation Wrap were wrapped with one application of wrap using the simultaneous wrapping method with an envelope fold. The contents of each package wrapped with HALYARD* Sequential Sterilisation Wrap were wrapped with two sheets of wrap using the sequential wrapping method with an envelope fold.

The following models of HALYARD* Sequential and ONE-STEP* Wraps were tested:

- H100 Sequential and ONE-STEP*
- H400 Sequential and ONE-STEP*
- H600 Sequential and ONE-STEP*[2]

This study consisted of a bracket approach for sterilant penetration determination for the HALYARD* Sequential and ONE-STEP* Sterilisation Wrap product line. Since the testing was completed for the heaviest and lightest weight models (H600 and H100 respectively), as well as for the mid-weight model (H400), this testing is representative of all models of the HALYARD* Sequential and ONE-STEP* wraps as follows: H100, H200, H300, H400, H500 and H600.

Test Methodology

The packages wrapped with Sequential and ONE-STEP* H100, H400, and H600 were sterilised using a pre-vacuum steam cycle at 132°C/270°F. The exposure time tested was 0.5 minutes, which is less than half of the standard hospital cycle for these conditions. Immediately following exposure (no drying time), the biological indicators were cultured for sterility.

Test Results

Biological indicator (BI) culture results show that all packs tested were sterile after an exposure time of 0.5 minutes at 132°C/270°F. The results of the sterility testing are presented in the table below, as the number of sterile packages out of the total number of packages tested:

Properties	Number of sterile packages at 0.5 minutes exposure time in a pre-vacuum steam cycle at 132°C/270°F
H100 ONE-STEP*	30 of 30
H400 ONE-STEP*	30 of 30
H600 ONE-STEP*	30 of 30
H100 SEQUENTIAL	30 of 30
H400 SEQUENTIAL	30 of 30
H600 SEQUENTIAL	30 of 30

Conclusions

HALYARD* Sequential and ONE-STEP* H100, H400, and H600 Sterilisation Wrap is validated for use with pre-vacuum steam sterilisation at 132°C/270°F for 4 minutes. (The half cycle was determined to be 0.5 minutes at the previously mentioned conditions.) This study consisted of a bracket approach for sterilant penetration determination for the Sequential and ONE-STEP* Sterilisation Wrap product line. Since this cycle is valid for the heaviest and lightest weight models (H600 and H100 respectively) and was confirmed by including the mid-weight model (H400), this cycle is valid for all models of the HALYARD* Sequential and ONE-STEP* wrap as follows: H100, H200, H300, H400, H500 and H600.

References

Nelson Laboratories Protocols: 200800957 REV 02, 200800958 REV 01
Nelson Laboratories Reports: 420406, 420410, 420416, 430208, 432434, 431529

APPENDIX 8: STERRAD® STERILISATION MPI STUDY RESULTS FOR HALYARD ONE-STEP*, QUICK CHECK* AND SMART-FOLD*

HALYARD SMART-FOLD* and all grades of HALYARD ONE-STEP* and QUICK CHECK* wrap is validated for use with all Advanced Sterilisation.

Products (ASP) STERRAD® Sterilisation Systems:

- STERRAD® 50, 100S and 200
- STERRAD® NX [Standard Cycle, Advanced Cycle]
- STERRAD® 100NX [Standard Cycle, Flex Cycle, EXPRESS Cycle, DUO Cycle]

Test Overview

A 1-year MPI test was performed on the ONE-STEP* and QUICK CHECK* Sterilisation Wrap models H100 through H500 and the SMART-FOLD* models H450 and H650 to provide testing documentation to support sterility for 1 year following use with the Advanced Sterilisation Products STERRAD® Sterilisation Systems.

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

- H100 – H600: APTIMAX® instrument tray (58 x 28 x 10cm) with Tray Mat, metal and non-metal instruments
- SMART-FOLD*: APTIMAX® instrument tray (58 x 28 x 10cm) with Tray Mat, metal and non-metal instruments

Test Results

The performance of the HALYARD ONE-STEP*, QUICK CHECK* and SMART-FOLD Sterilisation Wrap met all requirements when used with the Advanced Sterilisation Products STERRAD® Sterilisation Systems. Sterility of the package contents wrapped in the ONE-STEP*, QUICK CHECK* Sterilisation Wrap (H100-H500 grades) and SMART-FOLD* (H450 – 650) was maintained for 1 year post STERRAD® Systems sterilisation.

References

Halyard Test Reports: RP 03521/RPT 03521, RP 03491/RPT-03491, RP 03489/RPT-03489, RP 03493/RPT-03493, RP 03480/RPT-03480, RP-03487/RPT-03487, RP 03490/RPT-03490, RP 03488/RPT-03488, RP 03492/RPT- 03492, RP 03479/RPT-03479, RP-03481/RPT-03481, and RP-03486/RPT-03486; Laboratory Study Numbers: 588937, Study Report Numbers 1105-187, 1105-188, 1105-189, 1105-190, 1105-191, 1105-192, 1304-130, 1304-131, 1304-132 and 1304-133.

APPENDIX 9: AMSCO V-PRO STERILISATION MPI STUDY RESULTS OF HALYARD ONE-STEP* STERILISATION WRAP

HALYARD ONE-STEP* Sterilisation Wrap is validated to be used in the Amsco® V-PRO™ 1 Low Temperature Sterilisation System's cycle, Amsco® V-PRO™ 1 Low Temperature Sterilisation System's Lumen (identical to the V-PRO™ 1 Cycle) and Non Lumen Cycles, and the V-PRO™ Low Temperature Sterilisation System's Flexible Cycle. The wrap is intended to allow sterilisation of the enclosed medical device(s) until opened within the period of time for which performance data demonstrating the maintenance of sterility has been provided. The HALYARD ONE-STEP* Sterilisation Wrap was validated to be effectively aerated during the pre-programmed V-PRO™, V-PRO™ 1 Plus, and the V-PRO™ Flexible Sterilisation Cycles.

Maintenance of Package Sterility Recommendations

Non-sterile	Pre-vacuum Steam Sterilisation	EO Sterilisation	V-PRO Cycles
ONE-STEP* STERILISATION WRAP H100, H200, H300, H400, H500	At least 1 year	At least 1 year	At least 1 year

Wrap Model Recommendations for Amsco® V-PRO™ 1, V-PRO™ 1 Plus and Flexible Cycle1 Low Temperature Sterilisation System

ONE-STEP* Sterilisation Wrap Models	Intended Loads	Maximum Wrapped Package Content Weights Used in Sterility Maintenance Validation Study	Descriptions of Loads Used in Sterility Maintenance Validation Study[2]
H100	Very Light Weight Package (for example: batteries)	3 lbs (1.3 kg)	• 3 lbs metal mass (1.3 kg) • 6 forceps
H200	Light Weight Package (for example telescope with light cord)	6.5 lbs (2.9 kg)	• 2.5 lbs metal mass (1.1 kg) • 6 forceps • V-PRO tray (17" x 10"31/2"= 43 x 25.4 x 8.89 cm) at 4 lbs (1.8 kg)
H300	Light to Moderate Weight Package (for example general use medical instruments)	9 lbs (4.8 kg)	• 5 lbs metal mass (2.2 kg) • 6 forceps • V-PRO tray (17" x 10"31/2"= 43 x 25.4 x 8.89 cm) at 4 lbs (1.8 kg)
H400	Moderate to Heavy Weight Package (for example general use medical instruments)	10 lbs (4.5 kg)	• 6 lbs metal mass (2.7 kg) • 6 forceps • V-PRO tray (17" x 10"31/2"= 43 x 25.4 x 8.89 cm) at 4 lbs (1.8 kg)
H500	Heavy Weight Package (for example general use medical instruments)	10 lbs (4.5 kg)	• 5 lbs metal mass (2.2 kg) • 6 forceps • V-PRO tray (17" x 10"31/2"= 43 x 25.4 x 8.89 cm) at 5 lbs (2.2 kg)

1. Individual results may differ due to factors such as variations in handling practices, wrapping techniques, and folding methods. Results may also differ due to the use of irregularity shaped contents, which may put added stress on the wrap. Each healthcare facility should determine for itself which wrap grade is most appropriate for each intended use.
2. It is recommended to not exceed the maximum wrapped package content weights indicated for each wrap model. Furthermore, it is recommended to not exceed the number, weight, and size of individual content types that were validated for the HALYARD ONE-STEP* Sterilisation Wraps (i.e.,; the weight of the metal mass)

APPENDIX 10: STERILUCENT STERILISATION COMPATIBILITY AND MPI STUDY RESULTS FOR HALYARD ONE-STEP* STERILISATION WRAP

Test results validated that HALYARD ONE-STEP* Sterilisation Wrap (H100, H200, H300, H400 and H500) allowed sterilisation of the enclosed devices by the Sterilucent PSD-85 Hydrogen Peroxide Steriliser (i.e., both the Lumen and Non-Lumen Cycles). Additionally, the HALYARD ONE-STEP* Sterilisation Wrap was validated to allow effective aeration under the pre-programmed PSD-85 Sterilisation Cycles.

The PSD-85 Lumen Cycle has been validated to sterilise a load of up to ten (10) pounds (45 kg) (combined pouch and wrapped tray load) containing a maximum of ten (10) single channel stainless steel lumens per load with the following dimensions:

- An inside diameter of 1 mm or larger and a length of 60 mm or shorter
- An inside diameter of 2 mm or larger and a length of 250 mm or shorter
- An inside diameter of 3 mm or larger and a length of 350 mm or shorter

The PSD-85 Non-Lumen Cycle has been validated to sterilise a load of up to 25 pounds (11.3 kg) (combined pouch and wrapped tray load).

All models of the HALYARD ONE-STEP* Sterilisation Wrap (H100, H200, H300, H400 and H500) have been validated for use with the Sterilucent PSD-85 Hydrogen Peroxide Steriliser cycles in Table 1.

TABLE 1: Validated Sterilucent PSD-85 Hydrogen Peroxide Steriliser Cycle (Note: The instructions provided below are not intended to replace the detailed Instructions for Use provided with the Sterilucent PSD-85 Hydrogen Peroxide Steriliser.)

PSD-85 CYCLE	Intended Loads
LUMEN	Reusable metal and nonmetal devices including devices with diffusion-restricted spaces such as the hinged portion of forceps and scissors and up to 10 single channel stainless steel lumened devices of the following dimensions per chamber load: • An inside diameter of 1 mm or larger and a length of 60 mm or shorter • An inside diameter of 2 mm or larger and a length of 250 mm or shorter • An inside diameter of 3 mm or larger and a length of 350 mm or shorter (Refer to the PSD-85 User Manual for complete instructions on load(s) and cycle(s), including chamber loading instructions (i.e. 10 lbs per load = 4.5 kg))
NON-LUMEN	Non-lumened reusable metal and nonmetal devices including devices with stainless steel diffusion-restricted spaces such as the hinged portion of forceps and scissors. (Refer to the PSD-85 User Manual for complete instructions on load(s) and cycle(s), including chamber loading instructions (i.e. 25 lbs per load= 11.3 kg)

Summary of Nonclinical Tests

Performance of HALYARD ONE-STEP* Sterilisation Wrap (H100, H200, H300, H400, H500) has been tested in accordance with the applicable requirements recommended in Pre-Market Notification [510(k)] Submissions for Medical Sterilisation Packaging Systems in Health Care Facilities; Draft Guidance for Industry and FDA (March 7, 2002). All results of testing met acceptance criteria demonstrating that the HALYARD ONE-STEP* Sterilisation Wrap allows sterilisation of contents by Sterilucent PSD-85 Hydrogen Peroxide Steriliser and maintains sterility of contents until used.

Summary of Testing Performed	Results
Sterilucent System Sterilant Penetration	Passed
Material Compatibility/Biocompatibility – post-sterilisation (Cytotoxicity- ISO Elution, ISO Intracutaneous Reactivity, ISO guinea Pig Maximization Sensitization)	Passed
Performance Testing – Post-Sterilisation	Passed
Maintenance of Package Integrity (180 Days)	Passed

Overall Performance Conclusions

The nonclinical studies demonstrate that the HALYARD ONE-STEP* Sterilisation Wrap performs as intended as a sterilisation packaging system of medical devices when terminally sterilised in the Sterilucent PSD-85 Hydrogen Peroxide Steriliser (Lumen and Non-Lumen Cycles). These studies demonstrate that the HALYARD ONE-STEP* Sterilisation Wrap met the same criteria as the predicate devices and is substantially equivalent.

APPENDIX 11: ETHYLENE OXIDE STERILANT PENETRATION AND RESIDUALS STUDY RESULTS FOR HALYARD* SEQUENTIAL AND ONE-STEP* STERILISATION WRAP

Purpose

HALYARD* Sequential and ONE-STEP* Wrap was validated for use with ethylene oxide (EO) sterilisation to a sterility assurance level (SAL) of 10^{-6} using the biological indicator (BI) overkill method. Additionally, residual levels of ethylene oxide (EO) and ethylene chlorohydrin (ECH) were determined.

Test Samples

AAMI challenge test packs were assembled per AAMI ST41 section 6.6.1. Each test pack contained four cotton surgical towels, one 10 inch length of latex tubing, one PVC airway, two biological indicators inside needle-less 10 mL syringes, and two chemical integrators and were wrapped with Sequential and ONE-STEP* Sterilisation Wrap using the envelope fold.

The following models of Sequential and ONE-STEP* Wrap were tested:

- H100 Seqential and ONE-STEP*
- H400 Sequential and ONE-STEP*
- H600 Sequential and ONE-STEP*[1]

This study consisted of a bracket approach for sterilant penetration determination for the Sequential and ONE-STEP* Sterilisation Wrap product line. Since the testing was completed for the heaviest and lightest weight models (H600 and H100 respectively), as well as for the mid-weight model (H400), this testing is representative of all models of the Sequential and ONE-STEP* wrap as follows: H100, H200, H300, H400, H500, H600.

Test Methodology

The packages wrapped with Sequential and ONE-STEP* H100, H400, and H600 were sterilised using 100% ethylene oxide (EO) with a concentration of 725-735 mg/L at 55°C/131°F and 40% - 80% relative humidity. The exposure time tested was 30 minutes, which is half of the standard hospital cycle for these conditions. Immediately following exposure, the biological indicators were cultured for sterility.

After the half cycle was confirmed by at least three runs, another set of wrapped packages were exposed to full cycles (60 minutes). Immediately following sterilisation (0 hours aeration), the packs were tested for the amount of residual ethylene oxide (EO) and ethylene chlorohydrin (ECH). Additional packages were allowed to aerate for more typical time conditions (8 hours at 55°C and 12 hours at 43.3°C) and then tested.

1. Product availability may vary according to the location

Test Results

Biological indicator (BI) culture results from the half cycle determination runs show that all packs tested were sterile after an exposure time of 30 minutes. The results of the sterility testing are presented in the table below, as the number of sterile packages out of the total number of packages tested:

Properties	Number of sterile packages at 30 minutes exposure time in 100% ethylene oxide (EO) with a concentration of 725-735 mg/L at 55°C/131°F and 40% - 80% relative humidity
H100 QUICK CHECK (ONE-STEP*)	35 of 35
H400 ONE-STEP*	35 of 35
H600 ONE-STEP*	35 of 35
H100 SEQUENTIAL	35 of 35
H400 SEQUENTIAL	35 of 35
H600 SEQUENTIAL	35 of 35

As shown below, residuals analysis, after wrapped packages were exposed to full cycles (60 minutes), shows that, even with no aeration, the wrap is well below the ANSI/AAMI/ISO 10993-7 requirements of:

- less than 20 mg EO and
- less than 12 mg of ECH.

Aeration time and temperature	ONE-STEP* H100		Contents of H100 Pack					
			PVC airway		Latex Tubing		Towel	
	EO (mg)	ECH (mg)	EO (mg)	ECH (mg)	EO (mg)	ECH (mg)	EO (mg)	ECH (mg)
0 HOURS	0.215	0.151	5.564	0.024	13.991	0.128	0.606	5.220
8 HOURS, 55±4°C	0.299	0.192	0.724	<0.023	0.023	0.026	0.471	3.367
12 HOURS, 43.3±5°C	0.191	0.191	0.651	0.023	0.014	0.015	0.353	2.723

Aeration time and temperature	ONE-STEP* H400		Contents of H400 Pack					
			PVC airway		Latex Tubing		Towel	
	EO (mg)	ECH (mg)	EO (mg)	ECH (mg)	EO (mg)	ECH (mg)	EO (mg)	ECH (mg)
0 HOURS	0.328	0.746	4.697	0.023	6.936	0.102	0.427	3.624
9 HOURS, 55±4°C	0.356	0.356	0.637	<0.023	0.012	0.012	0.416	2.603
12 HOURS, 43.3±5°C	0.301	0.262	0.775	<0.023	0.023	0.015	0.410	3.803

Aeration time and temperature	ONE-STEP* H600		Contents of H600 Pack					
			PVC airway		Latex Tubing		Towel	
	EO (mg)	ECH (mg)	EO (mg)	ECH (mg)	EO (mg)	ECH (mg)	EO (mg)	ECH (mg)
0 HOURS	0.482	0.441	4.843	0.023	7.664	0.094	0.377	3.336
10 HOURS, 55±4°C	0.461	0.434	0.718	<0.023	0.016	0.016	0.340	2.509
12 HOURS, 43.3±5°C	0.411	0.411	0.676	<0.024	0.015	0.025	0.310	3.664

Aeration time and temperature	SEQUENTIAL H100		Contents of H100 Pack					
			PVC airway		Latex Tubing		Towel	
	EO (mg)	ECH (mg)	EO (mg)	ECH (mg)	EO (mg)	ECH (mg)	EO (mg)	ECH (mg)
0 HOURS	0.197	0.197	4.43	<0.023	6.79	0.086	0.415	3.61
11 HOURS, 55±4°C	0.227	0.227	0.573	0.023	0.034	<0.012	0.639	3.00
12 HOURS, 43.3±5°C	0.186	0.186	0.559	0.023	<0.012	<0.012	0.245	3.26

Aeration time and temperature	SEQUENTIAL H400		Contents of H400 Pack					
			PVC airway		Latex Tubing		Towel	
	EO (mg)	ECH (mg)	EO (mg)	ECH (mg)	EO (mg)	ECH (mg)	EO (mg)	ECH (mg)
0 HOURS	0.358	0.358	4.33	<0.023	7.03	0.086	0.562	4.73
12 HOURS, 55±4°C	0.339	0.339	0.427	<0.023	0.012	<0.012	0.882	0.973
12 HOURS, 43.3±5°C	0.488	0.329	0.465	0.023	0.022	0.012	1.08	1.15

Aeration time and temperature	SEQUENTIAL H600		Contents of H600 Pack					
			PVC airway		Latex Tubing		Towel	
	EO (mg)	ECH (mg)	EO (mg)	ECH (mg)	EO (mg)	ECH (mg)	EO (mg)	ECH (mg)
0 HOURS	0.490	0.484	4.55	<0.023	6.37	0.084	0.517	3.14
13 HOURS, 55±4°C	0.464	0.464	0.598	0.023	<0.012	<0.012	0.186	0.710
12 HOURS, 43.3±5°C	0.698	0.481	0.658	<0.023	0.019	<0.012	0.428	2.54

Conclusions

The validated ethylene oxide cycle for HALYARD* Sequential and ONE-STEP* H100, H400, and H600 is for 100% ethylene oxide (EO) with a concentration of 725-735 mg/L at 55°C/131°F and 40% - 80% relative humidity for 60 minutes, with aeration consisting of 8 hours at 55°C or 12 hours at 43.3°C. (The half cycle was determined to be 30 minutes at the previously mentioned conditions.) Additionally, residuals analysis shows that, even with no aeration, the wrap is well below the ANSI/AAMI/ISO 10993-7 requirements of less than 20 mg EO and less than 12 mg of ECH.

This study consisted of a bracket approach for sterilant penetration determination for the Sequential and ONE-STEP* Sterilisation Wrap product line. Since this cycle is valid for the heaviest and lightest weight models (H600 and H100 respectively) and was confirmed by including the mid-weight model (H400), this cycle is valid for all models of the HALYARD* Sequential and ONE-STEP* wrap as follows: H100, H200, H300, H400, H500 and H600.

References

Nelson Laboratories Protocols: 200803407 REV 01, 200900091 REV 01
Celabor Laboratories Reports: RAP- 20221926

APPENDIX 12: FORMALDEHYDE STERILISATION COMPATIBILITY AND RESIDUALS STUDY RESULTS FOR HALYARD* SEQUENTIAL AND ONE-STEP* STERILISATION WRAP

Purpose

HALYARD* has performed testing to investigate the durability, barrier and safety of HALYARD* Sequential and ONE-STEP* Wrap following formaldehyde sterilisation. Additionally, residual levels of formaldehyde in sterile Wrap were determined.

Test Samples

Samples from three lots of HALYARD* Sequential Sterile Wrap Products were tested prior and post low temperature steam and formaldehyde sterilisation. Two of these lots were subjected to one normal cycle of formaldehyde sterilisation. The third lot was subjected to two cycles of formaldehyde sterilisation.

Note: HALYARD* recommends that customers only subject the material to one cycle of sterilisation. The testing was conducted to demonstrate that the wrap materials remain stable and maintain integrity after the formaldehyde sterilisation process. The specific steps of this qualification are outlined in the Sterility Assurance Protocol, HCSA-04-003. Impact to durability, barrier, and safety were investigated in this qualification. The analysis was then reviewed against current claims. Any impact as a result of the low temperature steam and formaldehyde sterilisation was determined to be within acceptable limits as presented in the current Halyard Technical Data sheets for Sequential Sterilisation Wrap.

Durability Results: A visual inspection, grab tensile (CD), abrasion, and basis weight testing were performed on the samples. Samples remained intact with no major defects due to the formaldehyde sterilisation process. No statistically significant impact to abrasion and basis weight was noted in this study. Minimal impact was observed in grab tensile after 1X sterilisation (0-4%). After 2X sterilisation, an 11% decrease was noted. However, review of the data indicates this decrease to be acceptable for product performance and within the limits presented in the current Halyard Strength Technical Data sheet for HALYARD* Sequential Sterilisation Wrap.

Barrier Results: Bacterial Filtration Efficiency, hydrostatic head, and air permeability testing were performed on the samples. No statistical impact was seen during hydrostatic head testing. Minimal impact (1.0-1.4%) was seen on Bacterial Filtration Efficiency and within the limits presented in the current Halyard Barrier to Contamination Technical Data sheet for Sequential Sterilisation Wrap. A slight increase (0-3.5%) in air permeability was noted after 1X sterilisation. Impact to air permeability appears to make it worse after 2X sterilisation (10%).

Safety Results: Formaldehyde residuals, flammability, and gelbo lint testing were performed on the samples. Residuals were tested and determined to be within safe levels as noted in EN 14180. Formaldehyde sterilisation showed no impact to flammability. Minimal impact was observed with Gelbo Lint testing on one lot after 1X sterilisation cycle, however the actual number (average number of particles generated greater than 10 microns in size) is essentially the same. The unsterile sample averaged 0.65 particles versus 1.10 particles observed once sterilised.

Conclusions

It was concluded that the performance and safety of the sterilised wrap remained within acceptable limits. The Sterilisation Wrap products HALYARD* Sequential, ONE-STEP* and QUICK CHECK* are compatible with formaldehyde sterilisation. It is however recommended that users only subject the material of these devices to one cycle of sterilisation.

H200

		unsterile	Sterile 1X	ANOVA
Durability	Grab Tensile (lbs)	16.13	16.36	No Difference
	Abrasion (Rating)	4	3.75	
	Basis Weight (osy)	1.07	1.08	Sterile 1.8% higher
Barrier	Bacterial Filtration Efficiency (%)	97.6	96.2	Sterile 1.4% lower
	Hydrohead (mbars)	55.3	53.0	No Difference
	Air Perm (cfm)	69.6	71.5	No Difference
Safety	Formaldehyde Residuals	1.9	1.6	
	Flammability NFPA 702 (sec)	30	30	No Difference
	Gelbo Lint (Avg # particles> 10 µM)	1.05	1.20	No Difference

H400 (1X Sterile)

		unsterile	Sterile 1X	ANOVA
Durability	Grab Tensile (lbs)	30.6	29.3	Sterile 4.2% lower
	Abrasion (Rating)	5	5	No Difference
	Basis Weight (osy)	1.76	1.76	No Difference
Barrier	Bacterial Filtration Efficiency (%)	99.1	97.9	Sterile 1.2% lower
	Hydrohead (mbars)	67.8	66.0	No Difference
	Air Perm (cfm)	47.7	49.4	Sterile 3.5% higher
Safety	Formaldehyde Residuals	1.6	11.3	
	Flammability NFPA 702 (sec)	30	30	No Difference
	Gelbo Lint (Avg # particles> 10 µM)	0.65	1.10	Sterile 69%

H400 (2X Sterile)

		unsterile	Sterile 2X	ANOVA
Durability	Grab Tensile (lbs)	32.9	29.4	Sterile 10.6% less
	Abrasion (Rating)	4.96	5	
	Basis Weight (osy)	1.73	1.73	No Difference
Barrier	Bacterial Filtration Efficiency (%)	98.3	97.4	Sterile 0.9% lower
	Hydrohead (mbars)	64.0	61.3	No Difference
	Air Perm (cfm)	51.2	56.4	Sterile 10.2% higher
Safety	Formaldehyde Residuals	1	11	
	Flammability NFPA 702 (sec)	30	30	No Difference
	Gelbo Lint (Avg # particles> 10 µM)	0.85	0.60	No Difference

APPENDIX 13: EO AND PRE-VACUUM STEAM STERILISATION MPI STUDY RESULTS FOR HALYARD* ONE-STEP* AND SMART-FOLD* STERILISATION WRAP

Purpose

HALYARD ONE-STEP* Wrap was tested for performance in maintaining package integrity of sterilised wrapped packages for 30 days, 6 months and 1 year post-sterilisation. Sterilisation was performed using either pre-vacuum steam at 132°C/270°F for 4 minutes or using 100% ethylene oxide (EO) with a concentration of 725-735 mg/L at 55°C/131°F and 40% - 80% relative humidity for 60 minutes.

Test Samples

All 5 models of ONE-STEP* and SMART-FOLD* Wrap were tested:

- H100 ONE-STEP*
- H200 ONE-STEP*
- H300 ONE-STEP*
- H400 ONE-STEP*
- H500 ONE-STEP*
- H650 SMART-FOLD*

The table below indicates the package contents for each wrap model tested. Eight gauze stacks and one biological indicator were included in each package. The gauze stacks were positioned between the wrap and the package contents with four stacks on top and four on bottom and were used as the items for sterility testing. The biological indicators were placed in the centre of the packages and were used to verify the sterilisation cycle efficacy. The contents of each package wrapped with ONE-STEP* Sterilisation Wrap were wrapped with one application of wrap using the simultaneous wrapping method with an envelope fold. The ONE-STEP* results are also valid for QUICK CHECK* using one application and for Sequential or INTERLEAVED* using 2 applications.

ONE-STEP* and SMART-FOLD* Sterilisation Wrap Models	Intended Loads	Maximum Wrapped Package Content Weights Used in Sterility Maintenance Validation Study	Descriptions of Loads Used in Sterility Maintenance Validation Study
H100	Very Light Weight Package (for example: towel packs)	3 lbs (1.36 kg)	16 huck towels (17”x 29”) (43 x 73.6 cm)
H200	Light Weight Package (for example telescope with light cord)	6 lbs (2.7 kg)	2 huck towels (17”x 29”) (43 x 73.6 cm) 2 fluid resistant U-drape (68” x 109”) (172.7 x 276.8 cm) 1 fluid resistant universal bar drape (70” x 108”) (177.8 x 274.3 cm)
H300	Light to Moderate Weight Package (for example general use medical instruments)	9 lbs (4 kg)	**For Pre-Vacuum Steam:** 15 huck towels (17”x 29”) (43 x 73.6 cm) 1 small fluid resistant drape (60”x 76”) (152.4 x 193 cm) 5 lbs (2.26 kg) of metal mass **For EO:** 16 huck towels 2 fluid resistant large drapes (76” x 100”) (193 x 254 cm) 1 fluid resistant small drape (76” x 60”) (193 x 152.4 cm) 1 fluid resistant table cover (60” x 90”) (152.4 x 228.6 cm)
H400	Moderate to Heavy Weight Package (for example general use medical instruments)	13 lbs (5.9 kg)	4 tray liners 20” x 25” stacked (50.8 x 63.5 cm) 10” x 10” x 3 ½ “ (25.4 x 25.4 x 8.9 cm) tray containing 11 lbs (6.8 kg) of metal mass
H500	Heavy weight Package (for example general use medical instruments)	17 lbs (7.7 kg)	4 tray liners 20” x 25” stacked (50.8 x 63.5 cm) 10” x 10” x 3 ½ “ (25.4 x 25.4 x 8.9 cm) tray containing 15 lbs (6.8 kg) of metal mass
H650	Moderate to Heavy Weight Package (for example general use medical instruments)	25 lbs (11.3 kg)	4 tray liners 20” x 25” (50.8 x 63.5 cm) stacked in 10” x 10” (25.4 x 25.4 cm) tray containing 11 lbs (4.9 kg) of metal mass

Test Methodology

The wrapped packages were sterilised by either pre-vacuum steam at 132°C/270°F for 4 minutes or by 100% ethylene oxide (EO) with a concentration of 725-735 mg/L at 55°C/131°F and 40% - 80% relative humidity for 60 minutes. Following sterilisation and cooling or aeration, a designated number of packages (negative controls) were immediately tested for sterility to assure steriliser efficacy. Both the biological indicators and the gauze stacks from the negative controls were cultured to assure steriliser efficacy. Additional control packs of each wrap type were utilized to verify that the contamination could be detected, to ensure that wet packs (for pre-vacuum steam sterilisation) were not a source of contamination in the study, and to monitor bioburden levels throughout the study.

After sterilisation and cooling or aeration, the test packages were removed from the steriliser, underwent a series of handling and transport events based upon typical sterile package handling practices in hospitals over a 3-day period, and then were stored under controlled conditions simulating a hospital sterile storage environment. After 1 year of storage, representative sterilised packages were tested for sterility, wherein the 8 gauze stacks were removed from each test package and tested for the growth of microbial contaminants. The biological indicators from the test packages were also cultured to assure steriliser efficacy.

Test Results

The results of the sterility testing are presented in the table below, by sterilisation method, wrap model, and length of time stored:

Pre-Vacuum Steam Sterilisation

Wrap Model	Sterility Test Results with No Growth after 1 year
H100 ONE-STEP*	Pass
H200 ONE-STEP*	Pass
H300 ONE-STEP*	Pass
H400 ONE-STEP*	Pass
H500 ONE-STEP*	Pass
H650 SMART-FOLD*	Pass

Ethylene Oxide Sterilisation

Wrap Model	Sterility Test Results with No Growth after 1 year
H100 ONE-STEP*	Pass
H200 ONE-STEP*	Pass
H300 ONE-STEP*	Pass
H400 ONE-STEP*	Pass
H500 ONE-STEP*	Pass
H650 SMART-FOLD*	Pass

Conclusions

When sterilised with either pre-vacuum steam (at 132°C/270ºF for 4 minutes) or ethylene oxide (using 100% ethylene oxide with a concentration of 725-735 mg/L at 55°C/131°F and 40% - 80% relative humidity for 60 minutes), sterility of the package contents wrapped in all models ONE-STEP* Sterilisation Wrap models and SMART-FOLD* H650 was maintained for 1 year.

References

LexaMed Reports: 08-L046, 08-L047, 08-L048, 08-L049, 08-L088, 08-L089, 08-L090, 08-L091, 08-L129, 08-L130, 08-L131, 08L-132, 09-L001, 09-L024.

APPENDIX 14: ASEPTIC OPENING STUDY FOR QUICK CHECK* STERILISATION WRAP

Purpose

The objective of this study is to validate usability evaluation for aseptic presentation for HALYARD* Sterilisation Wrap by validating H400 QUICK CHECK* Sterilisation Wrap using UV powder (simulated germs) with the modified wrapping technique.

Test Methodology

A stainless-steel instrument tray was wrapped in HALYARD* H400 QUICK CHECK* Sterilisation Wrap using the modified wrapping technique. The package was closed using regular indicator tape. After closing the package, 30mg of UV powder (simulated germs) was spread on top of the closed package, afterwards the package was slid in a transport bag, carried around and manipulated. The package was removed from its transport bag and opened using regular aseptic opening technique.

Conclusion

After opening Halyard H400 QUICK CHECK* Sterilisation Wrap; there was no traces found of UV-Powder on the surface of the instrument basket, indicating the Sterilisation Wrap product was acceptable for opening aseptically.

References

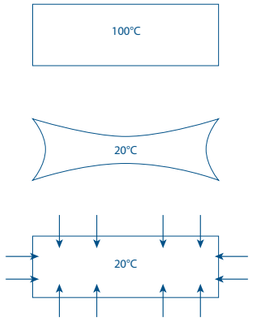
Protocol documents: Study Plan 34233, Study Plan 35146

APPENDIX 15: FINAL PACK TEST METHOD FOR HALYARD ONE-STEP* STERILISATION WRAP USING THE PRION CYCLE (18 MINUTES)

Background

The moment of the highest risk of contamination for a sterilised instrument set is during the removal from the autoclave. The package will cool down, this cooling down causes an under-pressure resulting in ambient air entering into the package.

The amount of airborne particles – including microorganisms – that are entering the package depends on the barrier retention properties of the packaging material.

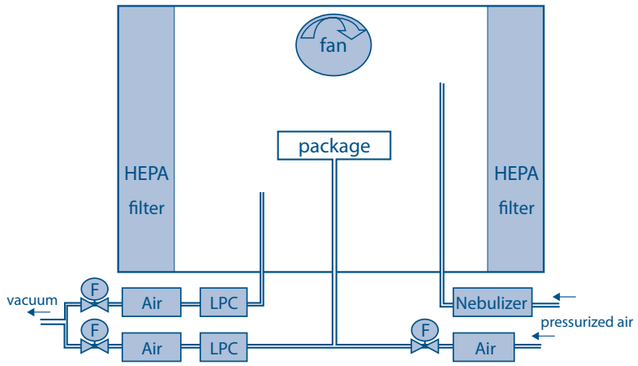


Test Methodology

Using this principle TNO, an independent research organisation based in the Netherlands, developed a bacterial barrier test. During the set-up of the test, the diffusional air flow rate is calculated: diffusional air flow represents the speed with which the air enters a sterilised package in the cooling down period. Diffusional flow was 250ml/minute for all types of ONE-STEP* Sterilisation material (H100, H200, H300, H400, H500).

In the first phase, instrument trays were packaged in HALYARD ONE-STEP* Sterilisation Wrap (H100, H200, H300, H400 and H500) and sterilised at 134°C during 18 minutes (prion cycle).

After sterilisation the wrapped sets were challenged with an aerosol of latex particles of 1µm at set diffusional flow rate of 250ml/minute. The particle concentration of the aerosol surrounding the package and in the sterilised package was determined with a Laser Particle Counter (LPC).



Conclusion

1. The conclusion of phase 1 and 2 is similar: HALYARD ONE-STEP* Sterilisation Wrap has an average retention percentage of >99.99% at a diffusional flow rate of 250ml/minute. This is better than the (statistically) required ≥99.9%.
2. The prolonged sterilisation cycle of 18 minutes did not affect barrier properties of HALYARD ONE-STEP* Sterilisation Wrap.
3. The prolonged storage period of three months did not affect barrier properties of HALYARD ONE-STEP* Sterilisation Wrap.

APPENDIX 16: WHOLE PACKAGE MICROBIAL CHALLENGE TEST FOR HALYARD* STERILISATION WRAP

Purpose

The purpose was to determine the microbial barrier efficiency of packaging material of HALYARD* Sterilisation Wrap by using the whole-package microbial aerosol challenge test.

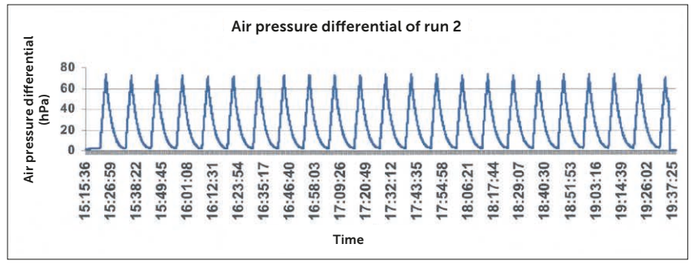
Test Methodology

Trays containing agar plates were wrapped in O&M Halyard* ONE-STEP* H200, H300, H400, H500, H600, and SMART-FOLD* H650 Sterilisation Wrap and sterilised. After sterilisation, the test packages were placed on the four levels of the shelving unit in the exposure chamber.

In the exposure chamber, 3ml per hour of a microbial suspension (microbial aerosol) was generated by a nebulizer. Packages were exposed to 23 periodic atmospheric pressure changes of 70hPA and to an airborne microbial challenge of Micrococcus luteus. Each test run lasted 4 hrs and 22 min.

After the exposure, the samples were incubated at 37°C for 72 hours to monitor the bacteria count, registered as Colony-Forming Units (CFU). Trays were opened and the agar plates were checked for bacterial growth.

Table: Periodic atmospheric pressure changes registered during a run



Test results HALYARD* Sterilisation Wrap

The test result has shown that O&M Halyard* ONE-STEP* and SMART-FOLD* Sterilisation Wrap achieves whole package filtration efficiency of >99.9999%, the highest score which can be reached on this test.

This methodology tests both the barrier efficiency of the material and the efficiency of the wrapping methods used.

Serial package number	1+2	3+4	5+6	7+8	9+10	11+12	13+14	15+16	17+18	Total 1 - 18
Air volume entering 2 packages (L)	10.244	10.244	10.244	10.244	10.244	10.244	10.244	10.244	10.244	92.195
Microbial challenge (CFU)	217.042	98.805	14.634	9.529	183.473	149.740	84.878	200.861	54.078	1.013.040
Whole Package Filtration Efficiency (%)	100	100	100	100	100	100	100	100	100	100

References

Report Allg.Hygiene und Umweltmedizin, Prof. Dr. Med. Hartmut Dunkelberg, Göttingen.

CE

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