HALYARD

COMPLIANCE TO EN ISO 11607-1:2006/ AMD 1:2014

“The manufacturer, Halyard Health, 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.”

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(NUMBERING FOLLOWS THE ORDER OF EN ISO 11607-1:2006)

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 centimeter
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
l :	Liter
lbs :	Pounds
LPS :	Laser Particle Counter
m^2 :	Square meter
mbar :	Millibar
MD tear :	Machine Direction
mg :	Milligram
ml :	Milliliters
mm :	Millimeter
µM :	Micrometer
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 11607-1:2006

INTRODUCTION

Dear Customer,

In July 2014, the technical committee ISO/TC 198 (Sterilisation of health care products) published the amendment of EN ISO 11607-1.

The major amendments to EN ISO 11607-1 are the altered definition of a microbial barrier.

The 2014 amendment of EN ISO 11607-1 refers to a microbial barrier as the property of the sterile barrier system which ensures that it prevents the ingress of microorganisms, demonstrated under test conditions which consider sterilisation process, handling, distribution, transport and storage.

Halyard Health always considered the new definition as being part of providing a proper microbial barrier; hence MPI (Maintenance of Package Integrity) testing has been performed on HALYARD* Sterilisation products prior to the revision of EN ISO 11607-1.

This document should resolve most of your questions. However, if you do have additional questions, please contact your local 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's clauses.

4. GENERAL REQUIREMENTS

4.2 Quality systems

4.2.1 The activities described in this part of EN ISO 11607 shall be carried out within a formal quality system.

HALYARD* Sterilisation products are manufactured in our US facility. This facility is certified by the following documents:

See Appendix 1: **ISO 13485: 2003 certificate**

4.3 Sampling

The sampling plans used for selection and testing of packaging systems shall be applicable to packaging systems 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

4.4.1 All test methods used to show compliance with this International Standard shall be validated and documented.

Test method	Test
ISO 6588-2	Colour leach
ASTM D3776–6M	Grammage
INDA Standard Test IST 160.1 (01)	Gelbo Lint
ISO 1974	MD Tear
ISO 1974	CD Tear
ISO 2758	Bursting Strength (dry)
ISO 3689	Bursting Strength (wet)
EN ISO 1924-2	Elongation (MD)
EN ISO 1924-2	Elongation (CD)
ISO 1924-2	MD Tensile Strength (dry)
ISO 1924-2	CD Tensile Strength (dry)
ISO 3781	MD Tensile Strength (wet)
ISO 3781	CD Tensile Strength (wet)
ISO 6588-2	pH
ISO 9197	Sodium Chloride content
ISO 9198	Sodium Sulphate content
DIN 58953-6:2010	Fluorescence
5514 FTMS No. 191A, INDA 80.4 -92	Hydrostatic Head Pressure
ASTM F2101	Bacterial Filtration Efficiency
Final Pack Method TNO	Microbial Barrier

4.4.2 Test method validation shall demonstrate the suitability of the methods as used. The following elements shall be included:

- *establishment of a rationale for the selection of the appropriate tests for the packaging system;*
- *establishment of acceptance criteria;*
- *determination of test method repeatability;*
- *determination of test method reproducibility;*
- *establishment of test method sensitivity for integrity tests.*

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

4.4.3 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.

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.

4.5 Documentation

4.5.1 Demonstration of compliance with the requirements of this part of EN ISO 11607 shall be documented.

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

The 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 AND PREFORMED 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 in order to ensure that:

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

5.1.4 As a minimum, the following shall be considered:

a) temperature range

Recommendations are:

- A temperature of 143°C (290°F) 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, do not sterilise at a set point below 55°C (131°F).

The ideal temperature range immediately prior to use is 20°C (68°F) to 23°C (73°F).

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.
The ideal humidity range immediately prior to use is ranging from 30% to 60%.

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 fluorescent 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 bio-burden 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 bio-burden levels on the wrap are not an issue for sterilisation.

See Appendix 2: Bioburden certificate dated March, 2015

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 finished product will consistently meet the requirements of this part of EN ISO 11607.

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 5.2)

The microbial barrier properties of the HALYARD* Sterilisation Wrap is validated using the Final Pack Method and Bacterial Filtration Efficiency test methods.

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

See Appendix 3: Physical Properties
See Appendix 14: Final Pack Test Method
See paragraph 5.1.9.d

b) biocompatibility and toxicological attributes

HALYARD* Sequential and ONE-STEP* 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 ONE-STEP* 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 Sequential and ONE-STEP* 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 Appendix 3 and 4 are included in EN 868-2:2009.
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 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 5: Ethylene Oxide Sterilant Penetration and Residuals Study Results for HALYARD* Sequential and ONE-STEP* Sterilisation Wrap
See Appendix 6: Pre-Vacuum Steam Sterilant Penetration Study Results for HALYARD* Sequential and ONE-STEP* Sterilisation Wrap
See Appendix 7: Formaldehyde Sterilisation Compatibility and Residuals Study Results for HALYARD* Sequential and ONE-STEP* Sterilisation Wrap
See Appendix 8: Sterilucent Sterilisation Compatibility And MPI Study Results for HALYARD ONE-STEP* Sterilisation Wrap
See Appendix 9: Sterrad® Sterilisation MPI Study Results for HALYARD ONE-STEP* and QUICK-CHECK* Sterilisation Wraps
See Appendix 10: Amsco V-Pro Sterilisation MPI Study Results Of HALYARD ONE-STEP* Sterilisation Wrap

f) any shelf-life limitations for pre-sterilisation and post-sterilisation storage

Healthcare facilities may use established event- and/or time-related protocols to monitor sterility maintenance of packages wrapped with the Sequential and ONE-STEP* 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, 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 ASTM 3776-6M.

See Appendix 12: 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 GELBO lint test (IST 160.1 (01)). 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: 2009.

See Appendix 3: Physical properties

f) Materials shall comply with 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: 2009.

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.

Sequential and ONE-STEP* 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 paragraph 5.1.6.b

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.

HALYARD* Sterilisation Wrap is not coated.

b) Coating mass shall be consistent with the stated value.

HALYARD* Sterilisation Wrap is not coated.

c) Materials shall demonstrate minimum specified seal strength when a seal is formed with another specified material under specified conditions.

HALYARD* Sterilisation wrap provides a full SBS, combination with protective packaging is left at the discretion of the end user.

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 preformed sterile barrier systems shall meet the requirements listed below.

a) 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 13: Executive Summary Colorfastness Study for HALYARD ONE-STEP* Sterilisation Wrap

b) If formed by sealing, the specified requirements for seal width and seal strength (tensile and/or burst) shall be met.

Not applicable.

c) Peel-open characteristics shall be continuous and homogeneous, without delamination or tearing of the material that can affect aseptic opening and presentation.

Not applicable.

d) Seals and/or closures shall provide a barrier to microorganisms.

The method of wrapping provides a tortuous path, which is a barrier to microorganisms. This was demonstrated via maintenance of package integrity testing.

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: Sterilucent Sterilisation Compatibility and MPI Study Results for HALYARD ONE-STEP* Sterilisation Wrap

See Appendix 9: Sterrad® Sterilisation MPI Study Results for HALYARD ONE-STEP* and QUICK-CHECK* Sterilisation Wraps

See Appendix 10: Amsco V-PRO Sterilisation MPI Study Results of HALYARD ONE-STEP* Sterilisation Wrap

See Appendix 11: EO and Pre-vacuum Steam Sterilisation MPI Study Results for HALYARD* Sequential and ONE-STEP* Sterilisation Wrap

See Appendix 14: Final Pack Test Method for HALYARD ONE-STEP* Sterilisation Wrap Using the Prion Cycle (18 minutes)

5.1.10 In addition to the requirements given in 5.1.1 through 5.1.7, reusable containers shall meet the requirements given below.

Not applicable

5.1.11 In addition to the requirements given in 5.1.1 through 5.1.7 and, if appropriate, 5.1.8, reusable fabrics shall meet the requirements given below:

HALYARD* Sterilisation Wrap is nonwoven material intended for single use.

5.2 Microbial barrier properties

5.2.1 The impermeability of a material shall be determined in accordance with Annex C.

KIMGUARD* is not impermeable. However, it has demonstrated excellent microbial barrier properties.

5.2.2 Demonstrating that the material is impermeable shall satisfy the microbial barrier requirement.

KIMGUARD* 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 in order to provide integrity of the sterile barrier system and product safety.

HALYARD* Sterilisation Wrap shows excellent microbial barrier properties as demonstrated in the Final Pack Test and bacterial filtration efficiency test performed as per ASTM F2101.

See Appendix 3: Physical properties

See Appendix 14: Final Pack Test Method

5.3 Compatibility with the sterilisation process

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

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 Sterilisation compatibility should be determined using a steriliser designed, constructed and operated in accordance with the requirements of the relevant International or European Standards.

The sterilisers (EO, pre-vacuum steam, hydrogen peroxide gas plasma) used in the compatibility tests are compliant with the requirements of the relevant International and European Standards.

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^{0}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^{0}C and 40% - 80% relative humidity for 60 minutes and subsequent aeration).

See paragraph 5.1.7 e.

5.3.5 Determination of suitability for the intended purpose shall include consideration of material variations that will occur during normal routine supply.

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

5.3.6 Where the product is enclosed by multiple wrappings or layers, different limits on material properties may be set for inner and outer layers.

The sterile barrier system of HALYARD* Sterilisation Wrap always consists of 2 layers of nonwoven wrap. Whether applied simultaneous or Sequential, wrapping techniques and the quality characteristics for both layers are identical.

5.4 Compatibility with the 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 ONE STEP* Sterilisation Wrap can be labelled with the statement "ONE-STEP* – Open Once" before use. HALYARD* Sequential is compatible with most sterilisation closure tapes. Writing should not be applied directly on the wrap.

See Appendix 13: Executive Summary Colorfastness Study for HALYARD ONE-STEP* Sterilisation Wrap

5.5 Storage and transport

5.5.1 Materials and preformed SBS shall be packaged to provide the protection necessary to maintain the performance characteristics during transport and storage.

The wraps are packaged in plastic shrink wrap (to maintain wrap cleanliness) and are then placed in a shipping case (to protect from ultraviolet light and damage during shipping/transport).

The transport packaging mentions the following information as per EN 868-2:2009:

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 condition

5.5.2 Materials and preformed sterile barrier systems shall be transported and stored under conditions that ensure that the performance characteristics remain within specified limits (see 5.1).

This can be accomplished by:

a) demonstrating retention of these characteristics under defined storage conditions

b) ensuring that storage conditions remain within specified limits.

Storage Prior to Use:

Location should be
- *clean*
- *dust-free*
- *away from fluorescent or ultraviolet light*

Use first in, first out (FIFO) stock rotation.

Prior to Use

- *Condition wrap at ideal temperature and humidity for a minimum of two hours.*
  - *Temperature 20°C to 23°C / 68°F to 73°F*
  - *Relative humidity ranging from 30% to 60%*
- *Examine wrap and discard if damage or extraneous matter is detected.*
- *Thoroughly clean and dry items to be wrapped/packaged*

APPENDIX 1: ISO 13485:2003 CERTIFICATE

bsi.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2003

This is to certify that:

Halyard Health, Inc.
5405 Windward Parkway
Alpharetta
Georgia
30004-3894
USA

Holds Certificate No: **FM 620884**

and operates a Quality Management System which complies with the requirements of ISO 13485:2003 for the following scope:

Please see scope page.

For and on behalf of BSI:

VP Regulatory Affairs, BSI Group America Inc.

Originally registered: 12/09/2014 Effective Date: 12/09/2014 Expiry Date: 01/09/2017

CMDCAS Recognized Registrar

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...making excellence a habit.

Certificate No: **FM 620884**

Registered Scope:

The design, manufacture, and distribution of surgical gowns, protective garments, face masks, surgical drapes, surgical packs, orthopedic soft goods, patient care products, cold therapy products, C-Section packs, OB Pack III, orthopedic packs, sterile enteral feeding and access devices; non sterile lavage systems and sample collection kits, non sterile safety drains for respiratory care; sterile pain management kits; sterile respiratory care packs; sterile anesthesia conduction needles and kits; saline vials, in vitro diagnostic test kits for gastroenterology; sterile gastro intestinal tubes and kits; sterile paracentesis trays and kits; sterile tracheostomy kits, tubes and cannulas. Temperature management systems for the areas of general surgery and general medical use; oral care kits; percussors; tracheal and oral suction systems and accessories, bal cath systems and endoscopic devices and accessories; RF Pain Management systems and accessories used within those systems; RF Pain Management cannulas/introducers, cooled and non-cooled probes, and tubing kits; RF Pain Management generators, pumps and pressure monitoring devices. The manufacture of sterilization wrap and non woven materials for medical devices.

Design and development of disposable elastomeric, mechanical and syringe infusion pumps (non-electric), pump fillers, administration sets, catheters, introducers (needles), dressing and convenience kits.

Originally registered: 12/09/2014 Effective Date: 12/09/2014 Expiry Date: 01/09/2017

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Certificate No: **FM 620884**

Location	Registered Activities
Halyard Health, Inc. 5405 Windward Parkway Alpharetta Georgia 30004-3894 USA	The design, manufacture, and distribution of surgical gowns, protective garments, face masks, surgical drapes, surgical packs, orthopedic soft goods, patient care products, cold therapy products, C-Section packs, OB Pack III, orthopedic packs, sterile enteral feeding and access devices; non sterile lavage systems and sample collection kits, non sterile safety drains for respiratory care; sterile pain management kits; sterile respiratory care packs; sterile anesthesia conduction needles and kits; saline vials, in vitro diagnostic test kits for gastroenterology; sterile gastro intestinal tubes and kits; sterile paracentesis trays and kits; sterile tracheostomy kits, tubes and cannulas. Temperature management systems for the areas of general surgery and general medical use; oral care kits; percussors; tracheal and oral suction systems and accessories, bal cath systems and endoscopic devices and accessories; RF Pain Management systems and accessories used within those systems; RF Pain Management cannulas/introducers, cooled and non-cooled probes, and tubing kits; RF Pain Management generators, pumps and pressure monitoring devices. The design and manufacture of sterilization wrap and non woven materials for medical devices. Design and development of disposable elastomeric, mechanical and syringe infusion pumps (non-electric), pump fillers, administration sets, catheters, introducers (needles), dressing and convenience kits.
Avent Inc. 6620 S. Memorial Place, Suite 100 Tucson Arizona 85756 USA	The manufacture and distribution of: Pain Management(including Sterile Anesthesia products) kits and associated components; in vitro diagnostic test kits for gastroenterology, Sterile Gastro Intestinal tubes and Kits; Sterile Paracentesis Trays and Kits; and sterile Respiratory Care packs (including tracheal kits, tubes and cannulas).
Avent S. de R.L. de C.V. Circuito Industrial No 40 Colonia Obrera Nogales CP 84048 Mexico	The manufacture and distribution of: Sterile Enteral Feeding and Access Devices; Sample Collection Kits; Non Sterile Safety Drains for Respiratory Care, sterile Pain Management Kits; and sterile Respiratory Care Packs (including tracheal tubes). This also includes Packaging and Warehouse activities at: Circuito Industrial No. 37 Colonia Obrera Nogales, Mexico CP 84048

Originally registered: 12/09/2014 Effective Date: 12/09/2014 Expiry Date: 01/09/2017

Certificate No: **FM 620884**

Location	Registered Activities
Avent de Honduras, S.A. de C.V. Carretera Tegucigalpa Villanueva Cortes Honduras	The manufacture and distribution of disposable sterile and non-sterile surgical gowns.
Avent S. de R.L. de C.V. AV. Hidalgo #6 Esq., Blvd., Luis Donaldo Colosio, Col. Educativa Nogales CP 84093 Mexico	The manufacture of disposable products including sterile and non-sterile surgical packs, gowns and components.
Avent S. de R.L. de C.V. Avenida El Castillo #17-B Nogales CP 84094 Mexico	The manufacture and distribution of sterile Respiratory Care Packs (including saline vials).
La Ada de Acuna Km. 4.5 Carreterra Presa La Amistad Ciudad De Acuna Coahuila 26220 Mexico	The manufacture of non-sterile face masks (surgical, isolation, industrial and respirator), surgical gowns, cold therapy products, and sterilization wrap. This also includes warehouse activities carried out at: 14 Finegan Road Del Rio TX 78840 USA
Avent R.L. de C.V. Carretera Internacional Salida Norte 1053 Magdalena CP 84160 Mexico	The manufacture and distribution of temperature management systems for the areas of general surgery and general medical use; oral care kits; percussors; tracheal and oral suction systems and accessories, bal-cath systems and endoscopic devices and accessories; RF Pain Management systems and accessories used within those systems; RF Pain Management cannulas/introducers, cooled and non-cooled probes, and tubing kits.
Halyard Health North Carolina, Inc. 389 Clyde Fitzgerald Road Linwood North Carolina 27299 USA	Manufacture of sterilization wrap and non woven materials for medical devices.

Originally registered: 12/09/2014 Effective Date: 12/09/2014 Expiry Date: 01/09/2017

Certificate No: **FM 620884**

Location	Registered Activities
Avent S. de R.L. de C.V. Ave Noruega Edificio D-1B Fraccionamiento, Rubio Tijuana B.C. 22116 Mexico	Manufacture of Disposable and Reusable Elastomeric, Mechanical and Syringe Infusion Pumps (Non-Electric), Pump Fillers, Administration Sets, Catheters, Introducers (Needles), Dressing, Convenience Kits. This also includes warehouse manufacture and labeling activity at: Avent S. de R.L. de C.V., Privada Baja California Edificio B2, Fraccionamiento, Rubio, Tijuana, B.C. Mexico, 22116
Halyard - Irvine 43 Discovery, Suite 100 Irvine California 92618 USA	Design and Development and Complaint Handling of Disposable Elastomeric, Mechanical and Syringe, Infusion Pumps (Non-Electric), Pump Fillers, Administration Sets, Catheters, Introducers (Needles), Dressings, Convenience Kits. This also includes the R & D Lab and Complaint Lab located at: 15440 Laguna Canyon, Suite 130 Irvine, CA 92618.

Originally registered: 12/09/2014 Effective Date: 12/09/2014 Expiry Date: 01/09/2017

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APPENDIX 2: BIOBURDEN CERTIFICATE

HALYARD

March 4, 2015

To Whom It May Concern:

Halyard Health produces Sterilization Wrap products that are monitored periodically for microbial bioburden levels. The product(s) is tested according to requirements of ANSI/AAMI/ISO 11737-1:2006/(R)2011 Sterilization of health care products—Microbiological methods—Part 1: Determination of the population of microorganisms on product.

The average CFU/gram for testing conducted during 2013-2014 is 31 CFU/gram.

I hope this information has been helpful.

Sincerely,

Christal Avery
Halyard North Carolina
Quality Manager

APPENDIX 3: PHYSICAL PROPERTIES

Physical Properties Test Methodology and Results for HALYARD ONE-STEP*/QUICK CHECK* H100 Sterilisation Wrap

Test	Methodology	Interpretation of Results	HALYARD OS/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.	98.9 %[4]
GRAB TENSILE	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.[5]	Higher numbers indicate a stronger fabric.	25.2 lbs[6]
RESISTANCE TO LINTING	In a controlled environment, a 9"X9" 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 average number of lint particles generated greater than 10 microns in size. [7]	Lower numbers in this test indicate less lint, which is desirable in the operating room environment.	3 particles[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.	59.5 mbar[6]
FLAMMABILITY	The fabric sample is held at a 45° angle and a standardized flame is applied to the bottom edge of the specimen for 30 seconds or until sustained ignition occurs, whichever comes sooner. Four classes are recognized by the National Fire Prevention Association (NFPA) for fabrics used for clothing: *Class 1: Slow burning fabrics which have a flame spread time of 20 seconds or more.* *Class 2: Moderately flammable fabrics which have a flame spread time of 8 to 19 seconds inclusive.* *Class 3: Relatively flammable fabrics which have a flame spread time of 3 to 7 seconds inclusive.* *Class 4: Dangerously flammable fabrics which have a flame spread time of less than 3 seconds.* Results are reported by classification and seconds until sustained ignition.[9]	A lower class (longer time) indicates a more flame resistant fabric.	Class 1 (30 sec.)[6]

1. The above results are averages based upon testing of representative samples selected randomly from distribution. Since HALYARD ONE-STEP* sterilisation wrap consists of two layers bonded together, all testing was conducted on two layers.
2. Nelson Laboratories, Inc., Salt Lake City, Utah, "Bacterial Filtration Efficiency," Procedure No. SOP/ARO/007I.1.
3. ASTM F2101-07. "Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus" 2007.
4. Test data generated by Nelson Laboratories, Inc., Salt Lake City, Utah via lab # 421675.
5. ASTM D5034-09 (2013). "Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test)".
6. Test data generated by Integrated Paper Services, Neenah, WI via request # 9051.
7. INDA Standard test IST 160.1:1995, "Resistance to Linting of Nonwoven Fabrics," 1995.
8. AATCC 127. "Water Resistance: Hydrostatic Pressure Test" 2003. "Standard Test Method for Repellency of Nonwoven Fabrics Using the Hydrostatic Pressure Test", IST 80.4, INDA Standard Tests.
9. NFPA 702-1980. "Flammability of wearing apparel".
10. Final Pack Method is developed by TNO (Netherlands Organization for Applied Scientific Research)
11. Test data generated by TNO (Netherlands Organization for Applied Scientific Research)

Physical Properties Test Methodology and Results for HALYARD ONE-STEP*/QUICK CHECK* H200 Sterilisation Wrap

Test	Methodology	Interpretation of Results	HALYARD OS/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.	99.7 %[4]
GRAB TENSILE	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.[5]	Higher numbers indicate a stronger fabric.	29.1 lbs[6]
RESISTANCE TO LINTING	In a controlled environment, a 9"X9" 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 average number of lint particles generated greater than 10 microns in size. [7]	Lower numbers in this test indicate less lint, which is desirable in the operating room environment.	4 particles[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.	77.4 mbar[6]
FLAMMABILITY	The fabric sample is held at a 45° angle and a standardized flame is applied to the bottom edge of the specimen for 30 seconds or until sustained ignition occurs, whichever comes sooner. Four classes are recognized by the National Fire Prevention Association (NFPA) for fabrics used for clothing: *Class 1: Slow burning fabrics which have a flame spread time of 20 seconds or more.* *Class 2: Moderately flammable fabrics which have a flame spread time of 8 to 19 seconds inclusive.* *Class 3: Relatively flammable fabrics which have a flame spread time of 3 to 7 seconds inclusive.* *Class 4: Dangerously flammable fabrics which have a flame spread time of less than 3 seconds.* Results are reported by classification and seconds until sustained ignition.[9]	A lower class (longer time) indicates a more flame resistant fabric.	Class 1 (30 sec.)[6]

1. The above results are averages based upon testing of representative samples selected randomly from distribution. Since HALYARD ONE-STEP* sterilisation wrap consists of two layers bonded together, all testing was conducted on two layers.
2. Nelson Laboratories, Inc., Salt Lake City, Utah, "Bacterial Filtration Efficiency," Procedure No. SOP/ARO/007I.1.
3. ASTM F2101-07. "Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus" 2007.
4. Test data generated by Nelson Laboratories, Inc., Salt Lake City, Utah via lab # 421675.
5. ASTM D5034-09 (2013). "Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test)".
6. Test data generated by Integrated Paper Services, Neenah, WI via request # 9051.
7. INDA Standard test IST 160.1:1995, "Resistance to Linting of Nonwoven Fabrics," 1995.
8. AATCC 127. "Water Resistance: Hydrostatic Pressure Test" 2003. "Standard Test Method for Repellency of Nonwoven Fabrics Using the Hydrostatic Pressure Test", IST 80.4, INDA Standard Tests.
9. NFPA 702-1980. "Flammability of wearing apparel".
10. Final Pack Method is developed by TNO (Netherlands Organization for Applied Scientific Research)
11. Test data generated by TNO (Netherlands Organization for Applied Scientific Research)

Physical Properties Test Methodology and Results for HALYARD ONE-STEP*/QUICK CHECK* H300 Sterilisation Wrap

Test	Methodology	Interpretation of Results	HALYARD OS/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.	99.9 %[4]
GRAB TENSILE	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.[5]	Higher numbers indicate a stronger fabric.	36.7 lbs[6]
RESISTANCE TO LINTING	In a controlled environment, a 9"X9" 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 average number of lint particles generated greater than 10 microns in size. [7]	Lower numbers in this test indicate less lint, which is desirable in the operating room environment.	1 particle[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.	85.2 mbar[6]
FLAMMABILITY	The fabric sample is held at a 45° angle and a standardized flame is applied to the bottom edge of the specimen for 30 seconds or until sustained ignition occurs, whichever comes sooner. Four classes are recognized by the National Fire Prevention Association (NFPA) for fabrics used for clothing: *Class 1: Slow burning fabrics which have a flame spread time of 20 seconds or more.* *Class 2: Moderately flammable fabrics which have a flame spread time of 8 to 19 seconds inclusive.* *Class 3: Relatively flammable fabrics which have a flame spread time of 3 to 7 seconds inclusive.* *Class 4: Dangerously flammable fabrics which have a flame spread time of less than 3 seconds.* Results are reported by classification and seconds until sustained ignition.[9]	A lower class (longer time) indicates a more flame resistant fabric.	Class 1 (30 sec.)[6]

1. The above results are averages based upon testing of representative samples selected randomly from distribution. Since HALYARD ONE-STEP* sterilisation wrap consists of two layers bonded together, all testing was conducted on two layers.
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3. ASTM F2101-07. "Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus" 2007.
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7. INDA Standard test IST 160.1:1995, "Resistance to Linting of Nonwoven Fabrics," 1995.
8. AATCC 127. "Water Resistance: Hydrostatic Pressure Test" 2003. "Standard Test Method for Repellency of Nonwoven Fabrics Using the Hydrostatic Pressure Test", IST 80.4, INDA Standard Tests.
9. NFPA 702-1980. "Flammability of wearing apparel".
10. Final Pack Method is developed by TNO (Netherlands Organization for Applied Scientific Research)
11. Test data generated by TNO (Netherlands Organization for Applied Scientific Research)

Physical Properties Test Methodology and Results for HALYARD ONE-STEP*/QUICK CHECK* H400 Sterilisation Wrap

Test	Methodology	Interpretation of Results	HALYARD OS/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.	99.9 %[4]
GRAB TENSILE	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.[5]	Higher numbers indicate a stronger fabric.	51.8 lbs[6]
RESISTANCE TO LINTING	In a controlled environment, a 9"X9" 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 average number of lint particles generated greater than 10 microns in size. [7]	Lower numbers in this test indicate less lint, which is desirable in the operating room environment.	1 particle[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.	88.6 mbar[6]
FLAMMABILITY	The fabric sample is held at a 45° angle and a standardized flame is applied to the bottom edge of the specimen for 30 seconds or until sustained ignition occurs, whichever comes sooner. Four classes are recognized by the National Fire Prevention Association (NFPA) for fabrics used for clothing: *Class 1: Slow burning fabrics which have a flame spread time of 20 seconds or more.* *Class 2: Moderately flammable fabrics which have a flame spread time of 8 to 19 seconds inclusive.* *Class 3: Relatively flammable fabrics which have a flame spread time of 3 to 7 seconds inclusive.* *Class 4: Dangerously flammable fabrics which have a flame spread time of less than 3 seconds.* Results are reported by classification and seconds until sustained ignition.[9]	A lower class (longer time) indicates a more flame resistant fabric.	Class 1 (30 sec.)[6]

1. The above results are averages based upon testing of representative samples selected randomly from distribution. Since HALYARD ONE-STEP* sterilisation wrap consists of two layers bonded together, all testing was conducted on two layers.
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3. ASTM F2101-07. "Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus" 2007.
4. Test data generated by Nelson Laboratories, Inc., Salt Lake City, Utah via lab # 421675.
5. ASTM D5034-09 (2013). "Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test)".
6. Test data generated by Integrated Paper Services, Neenah, WI via request # 9051.
7. INDA Standard test IST 160.1:1995, "Resistance to Linting of Nonwoven Fabrics," 1995.
8. AATCC 127. "Water Resistance: Hydrostatic Pressure Test" 2003. "Standard Test Method for Repellency of Nonwoven Fabrics Using the Hydrostatic Pressure Test", IST 80.4, INDA Standard Tests.
9. NFPA 702-1980. "Flammability of wearing apparel".
10. Final Pack Method is developed by TNO (Netherlands Organization for Applied Scientific Research)
11. Test data generated by TNO (Netherlands Organization for Applied Scientific Research)

Physical Properties Test Methodology and Results for HALYARD ONE-STEP*/QUICK CHECK* H500 Sterilisation Wrap

Test	Methodology	Interpretation of Results	HALYARD OS/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]
GRAB TENSILE	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.[5]	Higher numbers indicate a stronger fabric.	56.9 lbs[6]
RESISTANCE TO LINTING	In a controlled environment, a 9"X9" 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 average number of lint particles generated greater than 10 microns in size. [7]	Lower numbers in this test indicate less lint, which is desirable in the operating room environment.	2 particles[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.	109.4 mbar[6]
FLAMMABILITY	The fabric sample is held at a 45° angle and a standardized flame is applied to the bottom edge of the specimen for 30 seconds or until sustained ignition occurs, whichever comes sooner. Four classes are recognized by the National Fire Prevention Association (NFPA) for fabrics used for clothing: *Class 1: Slow burning fabrics which have a flame spread time of 20 seconds or more.* *Class 2: Moderately flammable fabrics which have a flame spread time of 8 to 19 seconds inclusive.* *Class 3: Relatively flammable fabrics which have a flame spread time of 3 to 7 seconds inclusive.* *Class 4: Dangerously flammable fabrics which have a flame spread time of less than 3 seconds.* Results are reported by classification and seconds until sustained ignition.[9]	A lower class (longer time) indicates a more flame resistant fabric.	Class 1 (30 sec.)[6]

1. The above results are averages based upon testing of representative samples selected randomly from distribution. Since HALYARD ONE-STEP* sterilisation wrap consists of two layers bonded together, all testing was conducted on two layers.
2. Nelson Laboratories, Inc., Salt Lake City, Utah, "Bacterial Filtration Efficiency," Procedure No. SOP/ARO/007I.1.
3. ASTM F2101-07. "Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus" 2007.
4. Test data generated by Nelson Laboratories, Inc., Salt Lake City, Utah via lab # 421675.
5. ASTM D5034-09 (2013). "Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test)".
6. Test data generated by Integrated Paper Services, Neenah, WI via request # 9051.
7. INDA Standard test IST 160.1:1995, "Resistance to Linting of Nonwoven Fabrics," 1995.
8. AATCC 127. "Water Resistance: Hydrostatic Pressure Test" 2003. "Standard Test Method for Repellency of Nonwoven Fabrics Using the Hydrostatic Pressure Test", IST 80.4, INDA Standard Tests.
9. NFPA 702-1980. "Flammability of wearing apparel".
10. Final Pack Method is developed by TNO (Netherlands Organization for Applied Scientific Research)
11. Test data generated by TNO (Netherlands Organization for Applied Scientific Research)

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

Test	Methodology	Interpretation of Results	HALYARD* SEQUENTIAL 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.	96.2 %[4]
GRAB TENSILE	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.[5]	Higher numbers indicate a stronger fabric.	12.6 lbs[6]
RESISTANCE TO LINTING	In a controlled environment, a 9"X9" 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 average number of lint particles generated greater than 10 microns in size. [7]	Lower numbers in this test indicate less lint, which is desirable in the operating room environment.	3 particles[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.	46.4 mbar[6]
FLAMMABILITY	The fabric sample is held at a 45° angle and a standardized flame is applied to the bottom edge of the specimen for 30 seconds or until sustained ignition occurs, whichever comes sooner. Four classes are recognized by the National Fire Prevention Association (NFPA) for fabrics used for clothing: *Class 1: Slow burning fabrics which have a flame spread time of 20 seconds or more.* *Class 2: Moderately flammable fabrics which have a flame spread time of 8 to 19 seconds inclusive.* *Class 3: Relatively flammable fabrics which have a flame spread time of 3 to 7 seconds inclusive.* *Class 4: Dangerously flammable fabrics which have a flame spread time of less than 3 seconds.* Results are reported by classification and seconds until sustained ignition.[9]	A lower class (longer time) indicates a more flame resistant fabric.	Class 1 (30 sec.)[6]

1. The above results are averages based upon testing of representative samples selected randomly from distribution. Since HALYARD Sequential sterilisation wrap consists of one layer, all testing was conducted on one layer. Two layers have been validated for wrapping.
2. Nelson Laboratories, Inc., Salt Lake City, Utah, "Bacterial Filtration Efficiency," Procedure No. SOP/ARO/007I.1.
3. ASTM F2101-07. "Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus" 2007.
4. Test data generated by Nelson Laboratories, Inc., Salt Lake City, Utah via lab # 421687.
5. ASTM D5034-09 (2013). "Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test)".
6. Test data generated by Integrated Paper Services, Neenah, WI via request # 9051.
7. INDA Standard test IST 160.1:1995, "Resistance to Linting of Nonwoven Fabrics," 1995.
8. AATCC 127-2003. "Water Resistance: Hydrostatic Pressure Test" 2003. "Standard Test Method for Repellency of Nonwoven Fabrics Using the Hydrostatic Pressure Test", IST 80.4, INDA Standard Tests.
19. NFPA 702-1980. "Flammability of wearing apparel".
10. Final Pack Method is developed by TNO (Netherlands Organization for Applied Scientific Research)
11. Test data generated by TNO (Netherlands Organization for Applied Scientific Research)

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

Test	Methodology	Interpretation of Results	HALYARD* SEQUENTIAL 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.	96.7 %[4]
GRAB TENSILE	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.[5]	Higher numbers indicate a stronger fabric.	14.3 lbs[6]
RESISTANCE TO LINTING	In a controlled environment, a 9"X9" 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 average number of lint particles generated greater than 10 microns in size. [7]	Lower numbers in this test indicate less lint, which is desirable in the operating room environment.	2 particles[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.	53.7 mbar[6]
FLAMMABILITY	The fabric sample is held at a 45° angle and a standardized flame is applied to the bottom edge of the specimen for 30 seconds or until sustained ignition occurs, whichever comes sooner. Four classes are recognized by the National Fire Prevention Association (NFPA) for fabrics used for clothing: *Class 1: Slow burning fabrics which have a flame spread time of 20 seconds or more.* *Class 2: Moderately flammable fabrics which have a flame spread time of 8 to 19 seconds inclusive.* *Class 3: Relatively flammable fabrics which have a flame spread time of 3 to 7 seconds inclusive.* *Class 4: Dangerously flammable fabrics which have a flame spread time of less than 3 seconds.* Results are reported by classification and seconds until sustained ignition.[9]	A lower class (longer time) indicates a more flame resistant fabric.	Class 1 (30 sec.)[6]

1. The above results are averages based upon testing of representative samples selected randomly from distribution. Since HALYARD* Sequential sterilisation wrap consists of one layer, all testing was conducted on one layer. Two layers have been validated for wrapping.
2. Nelson Laboratories, Inc., Salt Lake City, Utah, "Bacterial Filtration Efficiency," Procedure No. SOP/ARO/007I.1.
3. ASTM F2101-07. "Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus" 2007.
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9. NFPA 702-1980. "Flammability of wearing apparel".
10. Final Pack Method is developed by TNO (Netherlands Organization for Applied Scientific Research)
11. Test data generated by TNO (Netherlands Organization for Applied Scientific Research)

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

Test	Methodology	Interpretation of Results	HALYARD* SEQUENTIAL 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.	99.1 %[4]
GRAB TENSILE	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.[5]	Higher numbers indicate a stronger fabric.	17.2 lbs[6]
RESISTANCE TO LINTING	In a controlled environment, a 9"X9" 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 average number of lint particles generated greater than 10 microns in size. [7]	Lower numbers in this test indicate less lint, which is desirable in the operating room environment.	1 particle[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.	58.9 mbar[6]
FLAMMABILITY	The fabric sample is held at a 45° angle and a standardized flame is applied to the bottom edge of the specimen for 30 seconds or until sustained ignition occurs, whichever comes sooner. Four classes are recognized by the National Fire Prevention Association (NFPA) for fabrics used for clothing: *Class 1: Slow burning fabrics which have a flame spread time of 20 seconds or more.* *Class 2: Moderately flammable fabrics which have a flame spread time of 8 to 19 seconds inclusive.* *Class 3: Relatively flammable fabrics which have a flame spread time of 3 to 7 seconds inclusive.* *Class 4: Dangerously flammable fabrics which have a flame spread time of less than 3 seconds.* Results are reported by classification and seconds until sustained ignition.[9]	A lower class (longer time) indicates a more flame resistant fabric.	Class 1 (30 sec.)[6]

1. The above results are averages based upon testing of representative samples selected randomly from distribution. Since HALYARD* Sequential sterilisation wrap consists of one layer, all testing was conducted on one layer. Two layers have been validated for wrapping.
2. Nelson Laboratories, Inc., Salt Lake City, Utah, "Bacterial Filtration Efficiency," Procedure No. SOP/ARO/007I.1.
3. ASTM F2101-07. "Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus" 2007.
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5. ASTM D5034-09 (2013). "Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test)".
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7. INDA Standard test IST 160.1:1995, "Resistance to Linting of Nonwoven Fabrics," 1995.
8. AATCC 127-2003. "Water Resistance: Hydrostatic Pressure Test" 2003. "Standard Test Method for Repellency of Nonwoven Fabrics Using the Hydrostatic Pressure Test", IST 80.4, INDA Standard Tests.
9. NFPA 702-1980. "Flammability of wearing apparel".
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11. Test data generated by TNO (Netherlands Organization for Applied Scientific Research)

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

Test	Methodology	Interpretation of Results	HALYARD* SEQUENTIAL 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.	99.7 %[4]
GRAB TENSILE	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.[5]	Higher numbers indicate a stronger fabric.	24.3 lbs[6]
RESISTANCE TO LINTING	In a controlled environment, a 9"X9" 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 average number of lint particles generated greater than 10 microns in size. [7]	Lower numbers in this test indicate less lint, which is desirable in the operating room environment.	0 particle[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.	62.1 mbar[6]
FLAMMABILITY	The fabric sample is held at a 45° angle and a standardized flame is applied to the bottom edge of the specimen for 30 seconds or until sustained ignition occurs, whichever comes sooner. Four classes are recognized by the National Fire Prevention Association (NFPA) for fabrics used for clothing: *Class 1: Slow burning fabrics which have a flame spread time of 20 seconds or more.* *Class 2: Moderately flammable fabrics which have a flame spread time of 8 to 19 seconds inclusive.* *Class 3: Relatively flammable fabrics which have a flame spread time of 3 to 7 seconds inclusive.* *Class 4: Dangerously flammable fabrics which have a flame spread time of less than 3 seconds.* Results are reported by classification and seconds until sustained ignition.[9]	A lower class (longer time) indicates a more flame resistant fabric.	Class 1 (30 sec.)[6]

1. The above results are averages based upon testing of representative samples selected randomly from distribution. Since HALYARD* Sequential sterilisation wrap consists of one layer, all testing was conducted on one layer. Two layers have been validated for wrapping.
2. Nelson Laboratories, Inc., Salt Lake City, Utah, "Bacterial Filtration Efficiency," Procedure No. SOP/ARO/007I.1.
3. ASTM F2101-07. "Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus" 2007.
4. Test data generated by Nelson Laboratories, Inc., Salt Lake City, Utah via lab # 421687.
5. ASTM D5034-09 (2013). "Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test)".
6. Test data generated by Integrated Paper Services, Neenah, WI via request # 9051.
7. INDA Standard test IST 160.1:1995, "Resistance to Linting of Nonwoven Fabrics," 1995.
8. AATCC 127-2003. "Water Resistance: Hydrostatic Pressure Test" 2003. "Standard Test Method for Repellency of Nonwoven Fabrics Using the Hydrostatic Pressure Test", IST 80.4, INDA Standard Tests.
9. NFPA 702-1980. "Flammability of wearing apparel".
10. Final Pack Method is developed by TNO (Netherlands Organization for Applied Scientific Research)
11. Test data generated by TNO (Netherlands Organization for Applied Scientific Research)

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

Test	Methodology	Interpretation of Results	HALYARD* SEQUENTIAL 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.	99.5 %[4]
GRAB TENSILE	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.[5]	Higher numbers indicate a stronger fabric.	26.6 lbs[6]
RESISTANCE TO LINTING	In a controlled environment, a 9"X9" 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 average number of lint particles generated greater than 10 microns in size. [7]	Lower numbers in this test indicate less lint, which is desirable in the operating room environment.	1 particle[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.	79.1 mbar[6]
FLAMMABILITY	The fabric sample is held at a 45° angle and a standardized flame is applied to the bottom edge of the specimen for 30 seconds or until sustained ignition occurs, whichever comes sooner. Four classes are recognized by the National Fire Prevention Association (NFPA) for fabrics used for clothing: *Class 1: Slow burning fabrics which have a flame spread time of 20 seconds or more.* *Class 2: Moderately flammable fabrics which have a flame spread time of 8 to 19 seconds inclusive.* *Class 3: Relatively flammable fabrics which have a flame spread time of 3 to 7 seconds inclusive.* *Class 4: Dangerously flammable fabrics which have a flame spread time of less than 3 seconds.* Results are reported by classification and seconds until sustained ignition.[9]	A lower class (longer time) indicates a more flame resistant fabric.	Class 1 (30 sec.)[6]

1. The above results are averages based upon testing of representative samples selected randomly from distribution. Since HALYARD* Sequential sterilisation wrap consists of one layer, all testing was conducted on one layer. Two layers have been validated for wrapping.
2. Nelson Laboratories, Inc., Salt Lake City, Utah, "Bacterial Filtration Efficiency," Procedure No. SOP/ARO/007I.1.
3. ASTM F2101-07. "Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus" 2007.
4. Test data generated by Nelson Laboratories, Inc., Salt Lake City, Utah via lab # 421687.
5. ASTM D5034-09 (2013). "Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test)".
6. Test data generated by Integrated Paper Services, Neenah, WI via request # 9051.
7. INDA Standard test IST 160.1:1995, "Resistance to Linting of Nonwoven Fabrics," 1995.
8. AATCC 127-2003. "Water Resistance: Hydrostatic Pressure Test" 2003. "Standard Test Method for Repellency of Nonwoven Fabrics Using the Hydrostatic Pressure Test", IST 80.4, INDA Standard Tests.
9. NFPA 702-1980. "Flammability of wearing apparel".
10. Final Pack Method is developed by TNO (Netherlands Organization for Applied Scientific Research)
11. Test data generated by TNO (Netherlands Organization for Applied Scientific Research)

APPENDIX 4: CHEMICAL PROPERTIES

Properties	Specification	HALYARD* Sequential H100	HALYARD* Sequential H200	HALYARD* Sequential H300	HALYARD* Sequential H400	HALYARD* Sequential H500
NR. OF LAYERS		2	2	2	2	2
PH	EN ISO 868-2 ISO 6588-2	5-8	5-8	5-8	5-8	5-8
COLOUR LEACH	EN ISO 868-2 ISO 6588-2	No Leach	No Leach	No Leach	No Leach	No Leach
SODIUM CHLORIDE %	EN ISO 868-2 ISO 9197	<0.005	<0.005	<0.005	<0.005	<0.005
SODIUM SULPHATE %	EN ISO 868-2 ISO 9198	<0.005	<0.005	<0.005	<0.005	<0.005
FLUORESCENCE	EN ISO 868-2 DIN 58953-6	None	None	None	None	None

References:

Centexbel Summary :MG/HS07, 7094, 7195
Report Number MG/HS07

APPENDIX 5: 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 7.6.1. 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 geography

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 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
8 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
8 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
8 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
8 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
8 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 ºC or 12 hours at 43.3 ºC. (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

Nelson Laboratories Reports: 455561, 457003, 457004, 458664, 458666, 458667

APPENDIX 6: 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 66cm) 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/270ºF. 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.

[2] Product availability may vary according to the geography

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/270ºF. 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/270ºF
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/270ºF 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 7: FORMALDEHYDE STERILISATION COMPATIBILITY AND RESIDUALS STUDY RESULTS FOR HALYARD* SEQUENTIAL AND ONE-STEP* STERILISATION WRAP

Purpose

Halyard Health 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 Health 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, keeping in mind that HALYARD* Sterilisation Wrap products are not considered a medical device. 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> 10µM)	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> 10µM)	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> 10µM)	0.85	0.60	No Difference

APPENDIX 8: 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 (45kg) (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 (11.3kg) (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 = 45kg))
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= 11.3kg)

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 9: STERRAD® STERILISATION MPI STUDY RESULTS FOR HALYARD ONE-STEP*

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]*

In addition, Halyard Health has completed 180-Day/6-Month Maintenance of Package Integrity (MPI) testing on ONE-STEP* and QUICK CHECK* Sterilisation Wrap models H300, H400, H500 for use with Advanced Sterilisation Products STERRAD® Sterilisation Systems.

Test Overview:

A 6-month MPI test was performed on the ONE-STEP* and QUICK CHECK* Sterilisation Wrap models H300, H400 and H500 to provide testing documentation to support sterility for 180 days following use with the Advanced Sterilisation Products STERRAD® Sterilisation Systems. The table below summarizes the package contents for each wrap model tested in the STERRAD® System.

ONE-STEP* & QUICK CHECK* Sterilisation Wrap Models	Intended Loads	Weights of Wrapped Package Content Used in Validation Study (Total weight including tray)	Descriptions of Loads Used in Sterility Maintenance Validation Study
H300	Light to moderate weight package (e.g., general use medical instruments)	10.7 lbs. (4.8kg)	• APTIMAX® Instrument Tray (23 in. x 11 in. x 4 in. = 58.4x27.9x10.1cm)) with Tray Mat • Metal and non-metal instruments
H400	Moderate to heavy weight package (e.g., general use medical instruments)	10.7 lbs.	• APTIMAX® Instrument Tray (23 in. x 11 in. x 4 in.) with Tray Mat • Metal and non-metal instruments
H500	Heavy weight package (e.g., general use medical instruments)	10.7 lbs.	• APTIMAX® Instrument Tray (23 in. x 11 in. x 4 in.) with Tray Mat • Metal and non-metal instruments

Test Results:

The performance of the HALYARD ONE-STEP* and QUICK CHECK* 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* and QUICK CHECK* Sterilisation Wrap (H300-H500 grades) was maintained for 6 months (180 days) 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 10: 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

Models	Pre-Vacuum Steam Sterilisation	EO Sterilisation	V-PRO Cycles
ONE-STEP* STERILISATION WRAP MODELS H100 AND H200	At least 30 days	At least 30 days	At least 30 days
ONE-STEP* STERILISATION WRAP MODELS 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 (1.3kg)	• 3 lbs metal mass (1.3kg) • 6 forceps
H200	Light Weight Package (for example telescope with light cord)	6.5 lbs (2.9kg)	• 2.5 lbs metal mass (1.1kg) • 6 forceps • V-PRO tray (17"x10"31/2"= 43 x 25.4 x 8.89cm) at 4 lbs (1.8kg)
H300	Light to Moderate Weight Package (for example general use medical instruments)	9 lbs (4.8kg)	• 5 lbs metal mass (2.2kg) • 6 forceps • V-PRO tray (17"x10"31/2"= 43 x 25.4 x 8.89cm) at 4 lbs (1.8kg)
H400	Moderate to Heavy Weight Package (for example general use medical instruments)	10 lbs (4.5kg)	• 6 lbs metal mass (2.7kg) • 6 forceps • V-PRO tray (17"x10"31/2"= 43 x 25.4 x 8.89cm) at 4 lbs (1.8kg)
H400	Heavyweight Package (for example general use medical instruments)	10 lbs (4.5kg)	• 65 lbs metal mass (2.2kg) • 6 forceps • V-PRO tray (17"x10"31/2"= 43 x 25.4 x 8.89cm) at 5 lbs (2.2kg)

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 11: EO AND PRE-VACUUM STEAM STERILISATION MPI STUDY RESULTS FOR HALYARD* SEQUENTIAL AND ONE-STEP* STERILISATION WRAP

Purpose

HALYARD* Sequential Wrap was tested for performance in maintaining the package integrity of sterilised wrapped packages for 30 days post-sterilisation, and 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/270ºF 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 Sequential and ONE-STEP* Wrap were tested:

- *H100 Sequential and ONE-STEP**
- *H200 Sequential and ONE-STEP**
- *H300 Sequential and ONE-STEP**
- *H400 Sequential and ONE-STEP**
- *H500 Sequential and ONE-STEP**

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 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.

SEQUENTIAL and 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
H100	Very Light Weight Package (for example: towel packs)	3 lbs (1.36kg)	16 huck towels (17"x 29") (43 x 73.6 cm)
H200	Light Weight Package (for example telescope with light cord)	6 lbs (2.7kg)	2 huck towels (17"x 29") (43 x 73.6 cm) 2 fluid resistant U-drape (68"x109") (172.7 x 276.8cm) 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"x100") (193 x 254 cm) 1 fluid resistant small drape (76"x60") (193 x 152.4 cm) 1 fluid resistant table cover (60"x90") (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
H400	Heavyweight 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

Test Methodology

The wrapped packages were sterilised by either pre-vacuum steam at 132°C/270ºF 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 30 days 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 30 days	Sterility Test Results with No Growth after 1 year
H100 ONE-STEP*	Pass	Pass
H200 ONE-STEP*	Pass	Pass
H300 ONE-STEP*	Pass	Pass
H400 ONE-STEP*	Pass	Pass
H500 ONE-STEP*	Pass	Pass
H100 SEQUENTIAL	Pass	---
H200 SEQUENTIAL	Pass	---
H300 SEQUENTIAL	Pass	---
H400 SEQUENTIAL	Pass	---
H500 SEQUENTIAL	Pass	---

Ethylene Oxide Sterilisation

Wrap Model	Sterility Test Results with No Growth after 30 days	Sterility Test Results with No Growth after 1 year
H100 ONE-STEP*	Pass	---
H200 ONE-STEP*	Pass	---
H300 ONE-STEP*	Pass	Pass
H400 ONE-STEP*	Pass	Pass
H500 ONE-STEP*	Pass	Pass
H100 SEQUENTIAL	Pass	---
H200 SEQUENTIAL	Pass	---
H300 SEQUENTIAL	Pass	---
H400 SEQUENTIAL	Pass	---
H500 SEQUENTIAL	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 of Sequential and in ONE-STEP* Sterilisation Wrap models. H100 and H200 was maintained for 30 days (and 1 year for Pre-vacuum sterilisation) post sterilisation and sterility of the package contents for Sequential and ONE-STEP* Sterilisation Wrap models H300, H400, H500 was maintained for 30 days, 6 months and 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 12: BASIS WEIGHT OF MATERIALS NOT REQUIRING CONDITIONING

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

	H100 seq	H100 OS	H200 seq	H200 OS	H300 seq	H300 OS	H400 seq	H400 OS	H500 seq	H500 OS
AVG BW G/M^2	34,78	70,33	40,58	80,44	46,36	92,34	62,25	123,73	69,46	138,78
STD	0,56	2,37	0,62	1,19	1,09	1,26	1,42	1,89	1,34	2,67
%CV	2	3	2	1	2	1	2	2	2	2

APPENDIX 13: 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

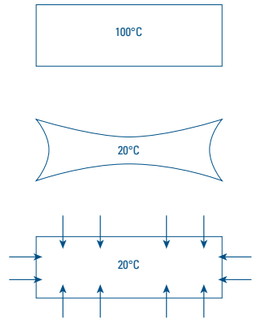
Average results for each model and sterilisation cycle are as follows:

	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 14: 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.

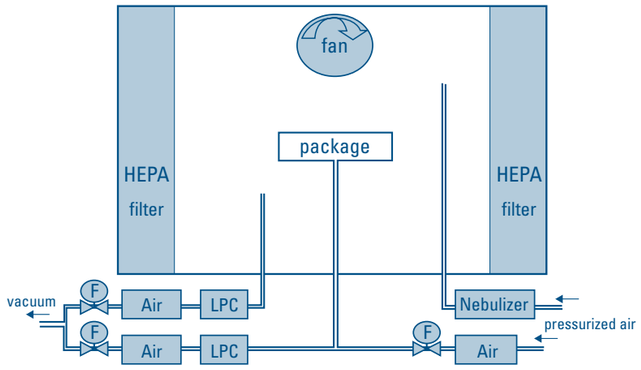
The amount of airborne particles – including microorganisms – that are entering the package depends on the barrier retention properties of the packaging material.

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.

Halyard Health is a medical technology company focused on advancing health and healthcare by delivering clinically superior products and solutions in infection prevention, surgical solutions, respiratory health, digestive health, IV therapy, and pain management. Halyard sells its recognized brands and products in more than 100 countries and holds leading market positions in multiple categories across the portfolio.

HALYARD Advantage*

Clinically Superior Products

Our products and solutions are high performance and high quality, and can be trusted to deliver optimal patient outcome.

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We truly care about our customers and their patients, going the extra mile to ensure they have the support they need, when they need it.

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We are experts in prevention and healing and recovery. We leverage that expertise to guide and problem-solve with our customers.

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