Sterilization Pouches & Reels

SATISFY YOUR STERILE PACKAGING NEEDS
FROM THE TIME OF ASSEMBLY, UNTIL ASEPTIC PRESENTATION AT THE POINT OF USE

STERIS is a global leader in infection prevention, decontamination, endoscope reprocessing, surgical equipment and service. STERIS is present in over 100 countries with production & manufacturing facilities in 17 countries and 12,000 employees worldwide. Inspired by our Customers' efforts to create a healthier and safer world, and guided by our legacy of leadership and innovation, we strive to be a Great Company. Holding one of the broadest portfolios of products in the industry, we pride ourselves on excellence, and our sterile barrier systems are no exception.

Descriptions

Sterilization Paper Reels are suitable for packaging extra-long products or creating individual pouches of special length. These single-use sterilization packaging are an economical and convenient way to package instruments, swabs and other items for sterilization.

- CE marked
- Medical grade paper 60 gsm
- Conform to ISO 11607-1 and 2, and EN 868-5
- Available in flat, or gusseted for larger objects
- Blue tinted, multi-layer, heat sealable PET/PP film
- Printed with Type 1 process indicators compliant with ISO 11140-1
- Manufactured under ISO 13485 quality system in a Class 9 Cleanroom
- Process indicators for Steam, EO and formaldehyde
- Constructed from high grade medical grade paper and multilayer transparent co-polymer
- Easy to seal with all types of sealing machines
- Strong seal strength
- Clean fibre-free opening

Order code description size qty

NWFL05100 Sterilization Reel (Flat) 5 cm x 100 m 1 Reel
NWFL05200 Sterilization Reel (Flat) 5 cm x 200 m 1 Reel
NWFL10100 Sterilization Reel (Flat) 10 cm x 100 m 1 Reel
NWFL10200 Sterilization Reel (Flat) 10 cm x 200 m 1 Reel
NWFL12100 Sterilization Reel (Flat) 12 cm x 100 m 1 Reel
NWFL12200 Sterilization Reel (Flat) 12 cm x 200 m 1 Reel
NWFL125200 Sterilization Reel (Flat) 12.5 cm x 200 m 1 Reel
NWFL15100 Sterilization Reel (Flat) 15 cm x 100 m 1 Reel
NWFL15200 Sterilization Reel (Flat) 15 cm x 200 m 1 Reel
NWFL20100 Sterilization Reel (Flat) 20 cm x 100 m 1 Reel
NWFL20200 Sterilization Reel (Flat) 20 cm x 200 m 1 Reel
NWFL25100 Sterilization Reel (Flat) 25 cm x 100 m 1 Reel
NWFL25200 Sterilization Reel (Flat) 25 cm x 200 m 1 Reel
NWFL30100 Sterilization Reel (Flat) 30 cm x 100 m 1 Reel
NWFL30200 Sterilization Reel (Flat) 30 cm x 200 m 1 Reel
NWFL35200 Sterilization Reel (Flat) 35 cm x 200 m 1 Reel
NWFL40200 Sterilization Reel (Flat) 40 cm x 200 m 1 Reel
NWFL42100 Sterilization Reel (Flat) 42 cm x 100 m 1 Reel
NWFL50100 Sterilization Reel (Flat) 50 cm x 100 m 1 Reel
NWFL75100 Sterilization Reel (Flat) 7.5 cm x 100 m 1 Reel
NWFL75200 Sterilization Reel (Flat) 7.5 cm x 200 m 1 Reel

Sterilization Paper Gusseted Pouches & Reels provide an effective solution for sterilization, safe handling, and storage of all items until the moment they are used.

- CE marked
- Manufactured under ISO 13485 quality system in a Class 9 Cleanroom
- Process indicators for Steam, EO and formaldehyde
- Constructed from high grade medical grade paper and multilayer transparent co-polymer
- Easy to seal with all types of sealing machines
- Strong seal strength
- Clean fibre-free opening

Order code description size qty

NWGP1030 Sterilization Pouch (Gusseted) 10 cm x 4 cm x 30 cm 1000/ Pack
NWGP1539 Sterilization Pouch (Gusseted) 15 cm x 5 cm x 39 cm 1000/ Pack
NWGP2039 Sterilization Pouch (Gusseted) 20 cm x 5 cm x 39 cm 500/ Pack
NWGP2045 Sterilization Pouch (Gusseted) 20 cm x 5 cm x 45 cm 500/ Pack
NWGP2048 Sterilization Pouch (Gusseted) 20 cm x 5 cm x 48 cm 500/ Pack
NWGP2545 Sterilization Pouch (Gusseted) 25 cm x 5 cm x 45 cm 500/ Pack
NWGP2548 Sterilization Pouch (Gusseted) 25 cm x 6 cm x 48 cm 500/ Pack
NWGP25645 Sterilization Pouch (Gusseted) 25 cm x 6.5 cm x 45 cm 500/ Pack
NWGP30760 Sterilization Pouch (Gusseted) 30 cm x 7 cm x 60 cm 500/ Pack

Sterilization Paper Pouches

- CE marked
- Custom sizes on request
- Suitable for steam, ethylene oxide and formaldehyde sterilisation
- Chevron-shaped end with thumbholes for ease of opening
- Manufactured from tinted, multilayer heat-sealable PET/PP film in a Class 9 Cleanroom
- Printed with Type 1 process indicators compliant with ISO 11140-1
- All pouches manufactured under ISO 13485 quality systems
- Medical grade paper 60 gsm
- Conform to ISO 11607-1 and 2, and EN 868-5

Order code description size qty

NWFP0520 Sterilization Pouch (Flat) 5 cm x 20 cm 1000/Pack
NWFP0525 Sterilization Pouch (Flat) 5 cm x 25 cm 1000/Pack
NWFP07517 Sterilization Pouch (Flat) 7.5 cm x 17 cm 1000/Pack
NWFP07520 Sterilization Pouch (Flat) 7.5 cm x 20 cm 1000/Pack
NWFP7520 Sterilization Pouch (Flat) 7.5 cm x 20 cm 1000/Pack
NWFP07525 Sterilization Pouch (Flat) 7.5 cm x 25 cm 1000/Pack
NWFP07527 Sterilization Pouch (Flat) 7.5 cm x 27 cm 1000/Pack
NWFP07530 Sterilization Pouch (Flat) 7.5 cm x 30 cm 1000/Pack
NWFP7535 Sterilization Pouch (Flat) 7.5 cm x 35 cm 1000/Pack
NWFP07540 Sterilization Pouch (Flat) 7.5 cm x 40 cm 1000/Pack
NWFP1020 Sterilization Pouch (Flat) 10 cm x 20 cm 1000/Pack
NWFP1026 Sterilization Pouch (Flat) 10 cm x 26 cm 1000/Pack
NWFP1030 Sterilization Pouch (Flat) 10 cm x 30 cm 1000/Pack
NWFP1035 Sterilization Pouch (Flat) 10 cm x 35 cm 1000/Pack
NWFP1040 Sterilization Pouch (Flat) 10 cm x 40 cm 1000/Pack
NWFP1050 Sterilization Pouch (Flat) 10 cm x 50 cm 1000/Pack
NWFP1230 Sterilization Pouch (Flat) 12 cm x 30 cm 1000/Pack

NWFP1240 Sterilization Pouch (Flat) 12 cm x 40 cm 1000/Pack
NWFP1520 Sterilization Pouch (Flat) 15 cm x 20 cm 1000/Pack
NWFP1525 Sterilization Pouch (Flat) 15 cm x 25 cm 1000/Pack
NWFP1530 Sterilization Pouch (Flat) 15 cm x 30 cm 1000/Pack
NWFP1535 Sterilization Pouch (Flat) 15 cm x 35 cm 1000/Pack
NWFP1538 Sterilization Pouch (Flat) 15 cm x 38 cm 1000/Pack
NWFP1540 Sterilization Pouch (Flat) 15 cm x 40 cm 1000/Pack
NWFP2040 Sterilization Pouch (Flat) 20 cm x 40 cm 1000/Pack
NWFP2128 Sterilization Pouch (Flat) 21 cm x 28 cm 1000/Pack
NWFP2135 Sterilization Pouch (Flat) 21 cm x 35 cm 1000/Pack
NWFP2142 Sterilization Pouch (Flat) 21 cm x 42 cm 1000/Pack
NWFP2535 Sterilization Pouch (Flat) 25 cm x 35 cm 1000/Pack
NWFP2540 Sterilization Pouch (Flat) 25 cm x 40 cm 1000/Pack
NWFP2550 Sterilization Pouch (Flat) 25 cm x 50 cm 1000/Pack
NWFP2745 Sterilization Pouch (Flat) 27 cm x 45 cm 1000/Pack
NWFP2835 Sterilization Pouch (Flat) 28 cm x 35 cm 1000/Pack
NWFP2840 Sterilization Pouch (Flat) 28 cm x 40 cm 1000/Pack
NWFP2848 Sterilization Pouch (Flat) 28 cm x 48 cm 1000/Pack
NWFP2850 Sterilization Pouch (Flat) 28 cm x 50 cm 1000/Pack
NWFP3040 Sterilization Pouch (Flat) 30 cm x 40 cm 1000/Pack
NWFP3045 Sterilization Pouch (Flat) 30 cm x 45 cm 1000/Pack
NWFP3050 Sterilization Pouch (Flat) 30 cm x 50 cm 1000/Pack
NWFP3245 Sterilization Pouch (Flat) 32 cm x 45 cm 1000/Pack
NWFP3250 Sterilization Pouch (Flat) 32 cm x 50 cm 1000/Pack
NWFP3260 Sterilization Pouch (Flat) 32 cm x 60 cm 1000/Pack
NWFP3550 Sterilization Pouch (Flat) 35 cm x 50 cm 1000/Pack
NWFP4260 Sterilization Pouch (Flat) 42 cm x 60 cm 1000/Pack

Sterilization Self-Seal Paper Pouches provide an effective solution for sterilization, safe handling and storage of all items until the moment they are used.

- CE marked
- No need for heat-sealing equipment
- Suitable for steam and EO sterilization
- Printed with ISO 11140-1 Type 1 indicators
- A wide range of sizes to accommodate user requirements
- Conform to ISO 11607-1 and 2, and EN 868-5
- Manufactured ISO 13485 quality systems in a Class 9 Cleanroom
- Comprising of 60 gsm medical grade paper and laminated film featuring a self-adhesive strip

Order code description size qty
NWKP0915 Sterilization Pouch (Self Seal) 9 cm x 15 cm 200/Pack
NWKP0923 Sterilization Pouch (Self Seal) 9 cm x 23 cm 200/Pack
NWKP0927 Sterilization Pouch (Self Seal) 9 cm x 27 cm 200/Pack
NWKP1036 Sterilization Pouch (Self Seal) 10 cm x 36 cm 200/Pack
NWKP1128 Sterilization Pouch (Self Seal) 11 cm x 28 cm 200/Pack
NWKP1325 Sterilization Pouch (Self Seal) 13 cm x 25 cm 200/Pack
NWKP1329 Sterilization Pouch (Self Seal) 13 cm x 29 cm 200/Pack
NWKP1336 Sterilization Pouch (Self Seal) 13 cm x 36 cm 200/Pack
NWKP1428 Sterilization Pouch (Self Seal) 14 cm x 28 cm 200/Pack
NWKP1430 Sterilization Pouch (Self Seal) 14 cm x 30 cm 200/Pack
NWKP1530 Sterilization Pouch (Self Seal) 15 cm x 30 cm 200/Pack
NWKP2033 Sterilization Pouch (Self Seal) 20 cm x 33 cm 200/Pack

NWKP2035 Sterilization Pouch (Self Seal) 20 cm x 35 cm 200/Pack
NWKP2042 Sterilization Pouch (Self Seal) 20 cm x 42 cm 200/Pack
NWKP3040 Sterilization Pouch (Self Seal) 30 cm x 40 cm 200/Pack
NWKP3042 Sterilization Pouch (Self Seal) 30 cm x 42 cm 200/Pack
NWKP7525 Sterilization Pouch (Self Seal) 7.5 cm x 25 cm 200/Pack

Manufacturing process

STERIS sterilization packaging is manufactured in the Mersin Free Zone Plant. The plant is ISO 9001 and ISO 13485 certified. As a requirement for certification, the plant has an established Quality System Manual.

The site strictly complies with the environmental, health and safety regulations in force and the production plant conforms with Clean Room HVAC System Performance Qualifications according to ISO14644-1. The regulations and norms of standards at all level are followed from purchase of raw materials to the shipment of final STERIS-branded products.

As a requirement of ISO 11607-2 all equipment, machines and processes used for manufacturing of STERIS products are validated. Standard Operation Procedure (SOP), general validation plan and IQ, OQ and PPQ plans and reports for manufacturing equipment are frequently updated and revised by our Quality Assurance Department.

In-house laboratory

The product facilities benefit from and in-house laboratory providing state-of-the-art product quality control. Trained and specialized personnel are on hand to conduct the various sterilization packaging tests required by relevant product standards and can test chemical indicator performance according to ISO 11140-1.

In accordance with ISO 11140-1 all chemical indicator performance tests are conducted in a resistometer which conforms to ISO 18472. These highly accurate, computerized test autoclaves with adjustable sterilization parameters are specially designed for biological and chemical indicator testing.

Product description

STERIS sterilization reels and pouches are registered under Class 1 as accessories in compliance with the European Medical Device Directive 93/42/EEC and 2007/47/EC. The compliance with the directive is shown by CE mark printed on the shipping carton labels.

STERIS sterilization packaging is constructed of transparent multilayer PET/PP copolymer film web and medical grade paper in compliance with EN 868-3. Chemical process indicators are applied on the paper surface for intended sterilization methods.

Standard STERIS sterilization packaging is constructed of 60gr medical grade paper with steam and ethylene oxide process indicators and PET/PP film web.

STERIS sterilization packaging is available with 60gr medical grade paper and with selectable imprinted chemical process indicator for steam, ethylene oxide and formaldehyde sterilization methods.

Intended use

STERIS sterilization reels and pouches are intended for use at packaging of medical devices to be sterilized in steam, ethylene oxide or formaldehyde sterilizers. Sterilization packaging will maintain its sterility until point of use.

Sterilization method

STERIS sterilization reels and pouches are designed to be used at steam, ethylene oxide and formaldehyde sterilizers. The sterilization packaging provides a protection of the medical device from contamination of bacteria by its high and proven microbial barrier properties and will keep its sterility after successful sterilization until use of the sterilized medical device.

To ensure optimum sterility conditions, instructions for use, handling and storage condition recommendations should be taken in consideration and followed.

Characteristics of the packaging

STERIS sterilization reels and pouches are designed, produces and distributed to provide highest quality standards.

The main characteristics of the packaging are.

- 3 independent seal lines
- Tear free 5 layers PET/PP film web
- Clean peel for aseptic presentation
- Proven microbial barrier properties
- Lead free water based chemical indicator
- Clear and accurate indicator colour change
- Wide range of product sizes and types

Instructions for use

STERIS sterilization pouches are ready for use. Sterilization reels need to be cut to required length and sealed at one end to form a ready to fill pouch.

1) Sharp ends of instruments must be covered with an instrument protector to prevent puncturing or cutting.
2) The medical device to be sterilized must be placed in the pouch and it should not be filled more than 75% of its capacity.
3) A gap of minimum 1.5cm between the material and each seal edge of the pouch must be left for a smooth airflow.
4) Before sealing, as much air as possible must be removed from the pouch.
5) The filled pouch has to be sealed with a calibrated and validated heat sealer according to the manufacturer's recommendation. STERIS sterilization packaging is suitable for sealing between 180°C up to 190°C. Strength of the seal must assure a clean peel.
6) During the handling seal stress must be avoided by filling the pouch horizontally or by working on a flat surface.
7) When loading into the sterilizer the pouches have to be placed into the basket in a way that film faces film and paper side faces paper side.
8) Sterilization pouches should be put upright in the basket or container and not too tight together so such that a hand can slide in between them.
9) Process the load according to established internal procedures.
10) Handle pouches with care when removing from the sterilizer to prevent puncturing or tearing. Store pouches in an area protected from sunlight, water and other liquids.
11) Do not use wet pouches. In case of wet pouches, change the packaging and repeat the sterilization process.
12) To open the pouch, use thumb and index finger to hold plastic side of the pouch and thumb and index finger to pull back the paper side of the pouch. Always open the pouch towards the opening direction. Open the pouch slowly for a clean and aseptic presentation.

Restrictions in use

STERIS sterilization reels and pouches are not designed to be used in dry heat, vaporized hydrogen peroxide gas plasma and gamma sterilization due to product's technical specifications. Packaging alternatives suitable for mentioned sterilization methods should be selected.

Medical grade paper

Medical grade paper with highest microbial barrier properties is used as bottom web for STERIS sterilization packaging. The dense and matted layer structure of cellulosic fibres allows the sterilization agent to pass inside the package and creates at the same time a blocking path for microorganism after sterilization.

STERIS medical grade paper is available in 60gr and is suitable for steam, ethylene oxide and formaldehyde sterilization methods.

Properties medical grade paper

STERIS uses highest quality medical grade paper for STERIS-branded sterilization reels and pouches. Medical grade paper is in compliance to requirements defined by European Standard EN 868-3 and all requirements listed in technical data sheet are fulfilled at any time

Chemical indicator

STERIS sterilization reels and pouches are imprinted with water based, non-toxic Type 1 chemical process indicators. The indicators are in compliance with ISO 11140-1 and fulfil the requirements of related standard.

STERIS standard sterilization packaging is imprinted with steam and ethylene oxide chemical process indicators. Chemical indicator for formaldehyde sterilization method is available upon request.

Colour change of chemical indicators

STERIS chemical process indicators provide a clear and accurate colour change after successful sterilization.

Sterilization Method	PRE Sterilization	POST Sterilization
Steam		
Ethylene Oxide		
Formaldehyde		

Indicator performance testing

Chemical process indicators are defined by the international standard ISO 11140-1 and must fulfil the requirements at all time. STERIS chemical process indicators are tested by an independent laboratory for performance requirements according ISO 111401-1.

Steam indicator performance testing

The test results obtained by an independent test laboratory verify that STERIS steam chemical process indicators fulfil the performance requirements defined by ISO 11140-1.

Testing Results

Test Environment	Test Time	Test Temperature	Test Result
Saturated Steam (Pass Cycle)	10.0 min ± 5 sec	121°C (+3/0°C)	Acceptable
Saturated Steam (Fail Cycle)	3.0 min ± 5 sec	121°C (+3/0°C)	Acceptable
Saturated Steam (Pass Cycle)	2.0 min ± 5 sec	134°C (+3/0°C)	Acceptable
Saturated Steam (Fail Cycle)	0.5 min ± 5 sec	134°C (+3/0°C)	Acceptable
Dry Heat	30.0 min ± 1 min	140°C (+2/0°C)	Acceptable

Ethylene oxide indicator performance testing

The test results obtained by an independent test laboratory verify that STERIS ethylene oxide chemical process indicators fulfil the performance requirements defined by ISO 11140-1.

TESTING RESULTS

Test Environment	Test Time	Test Temperature	RH%	Gas Concentration mg/L	Test Result
Absence of EO Gas	90 min ± 1 min	60°C ± 2°C	≥ 85%	None	Acceptable
EO Gas Test At:	2 min ± 15 s	54°C ± 1°C	60% ± 10% RH	600mg/L ± 30 mg/L	Acceptable
EO Gas Test At:	20 min ± 15 s	54°C ± 1°C	60% ± 10% RH	600mg/L ± 30 mg/L	Acceptable
EO Gas Test At:	5 min ± 15 s	30°C ± 1°C	60% ± 10% RH	600mg/L ± 30 mg/L	Acceptable
EO Gas Test At:	30 min ± 15 s	30°C ± 1°C	60% ± 10% RH	600mg/L ± 30 mg/L	Acceptable

Formaldehyde indicator performance testing

The test results obtained by an independent test laboratory verify that STERIS formaldehyde chemical process indicators fulfil the performance requirements defined by ISO 11140-1.

Testing Results Per Ansi/AAMI/ISO 11140-1

Test Environment	Test Time	Test Temperature	Gas Concentration mol/L	Results
Absence of formaldehyde	90 min ± 1 min	80°C ± 2°C	None	Acceptable Result
Formaldehyde:	20 s ± 5 s	60°C ± 0.5°C	1.0 mol/L ± 0.01 mol/L	Acceptable Result
Formaldehyde	15 min ± 15 sec	70°C ± 2°C	1.0 mol/L ± 0.01 mol/L	Acceptable Result

Laminated PET/PP film web

The film web used for STERIS sterilization reels and pouches are constructed of transparent, reinforced multilayer (five) laminated PET/PP (Polyester/Polypropylene) film. STERIS is one of three global manufacturers specialized for PP film extrusion for steam sterilization.

STERIS developed a special PP film for steam sterilization with exceptionally sealing performance by increased bondability, tensile strength and melting point. STERIS PET/PP films provide excellent mechanical strength, are easy sealable and peelable with uncoated medical grade paper.

The special film ensures high puncture, tear and break resistance pre and POST steam sterilization. PET/PP film web is suitable for steam, ethylene oxide and formaldehyde sterilization methods.

Properties of PET/PP film beb

STERIS uses highest quality PET/PP film webs for STERIS-branded sterilization reels and pouches. The film web is in compliance to requirements defined by European Standard EN 868-5 and all properties listed in technical data sheet are fulfilled at any time.

Final product testing

STERIS first priority is to meet customer expectations by highest quality and standard conform products. Implemented and applied quality control stages and in-house and/or external laboratory tests help us to ensure high product quality and sustainable production outcome. All final product of STERIS sterilization packaging are tested for compliance to ISO 11607-1, ISO 11140-1 and EN 868-5.

Final product specifications

Quality control testing is applied during various manufacturing stages and to the final product in determined frequencies. STERIS sterilization reels and pouches specific properties listed in below table are fulfilled at any time.

Properties	Unit	Value	Method	Frequency
Seal Width	mm	10±2 mm	EN 868-5	For film and paper changes & every 2 hours
Bubble Test	pcs	No leakage acc. Standard	ASTM F2096-04	Film and paper changed
Pinhole Determination	pcs	No pinhole acc. Standard	EN 868-5	Each film roll
Dimension Control	cm	Refer to internal documentation	ASTM F2203-02 (13)	Film and paper changed
Leakage Test	pcs	No seal leaks acc. Standard	ASTM F 1929-98 (15)	Film and paper changed
Peel Direction	pcs	No fibers on the testing tape	EN 868-5	Each printed roll
Steam Indicator Control	pcs	Color change from pink to brown	Visual	Each printed roll
EO Indicator Control	pcs	Color change from green to yellow	Visual	Each incoming material lot
FO Indicator Control	pcs	Color change from pink to green	Visual	Each incoming material lot
PET/PE film Bond Strength	N/15 mm	>2,7 n/15 mm	ASTM F88	Each film roll
PET/PE film Delaminating	pcs	None allowed	Steam Sterilization 134 °C/ 3.5min	Each film roll
Aseptic Presentation	pcs	No film or paper tear	Peel off / open slow	Each 2 hour of production
Bioburden Testing	pcs	Run and record	ISO 11737-1	At least every 3 months
Particles/Cleanliness	pcs	None allowed	Visual	Each 2 hour of production
Microbial Barrier	pcs	Fulfill requirements of ASTM F1608	ASTM F 1608	Internal determined period
Wrinkles in Films or Seals	pcs	None allowed	Visual	Each 2 hour of production
Jagged Edges	pcs	None allowed	Visual	Each 2 hour of production
Stewed Printing	pcs	±2 mm	Visual	Each printed roll
Print Image	pcs	Artwork and readable	Visual	Each printed roll

Sterilization efficacy validation test

Sterilization efficacy validation tests are used to determine the efficiency of medical sterilization packaging systems by processing them in a steam and ETO sterilizer validated to a sterility assurance level (SAL). Packaging are expected to meet the SAL at half cycle exposure time. On this reports, Sterilization efficacy of STERIS sterilization pouches were determined by the overkill method per AAMI and ISO guidelines. STERIS pouches were processed in steam and ETO sterilization cycle which is validated to a SAL of 10-6 Geobacillus stearothermophilus spores for steam and Bacillus atrophaeus for ETO sterilization. The SAL were achieved by inoculating of these spores in the most difficult locations to sterilize and sealing them within STERIS sterilization pouches. The pouches were processed at one-half the expected full cycle exposure time. Following exposure, the biological indicators were aseptically transferred to culture media and incubated as required. With this test method, sterilization was accomplished by demonstrating that a minimum 10-6 spores were successfully killed in half cycle both in steam and ETO sterilization.

Bioburden properties

The term bioburden is used to describe the population of viable microorganisms present on or in product and/or a sterile barrier system. STERIS sterilization reels and pouches have been tested for bioburden after manufacturing process according ISO 11737-1 standard by an independent and accredited test laboratory. STERIS sterilization

packaging is produced in a controlled and clean environment and provides a safe and effective barrier against microorganism by no bacteria growth.

Microbial barrier properties

STERIS sterilization reels and pouches are proven and effective microbial barriers. STERIS sterilization packaging has been tested for determining the microbial barrier properties, following steam and ETO sterilization by an external and accredited laboratory in the USA.

Sterilization packaging samples have been subjected to an aerosol of 1x107 Bacillus atrophaeus after processed in a steam sterilization cycle at 132˚C for 4 minutes exposure time. Each packaging sample was loaded with stainless steel coupons, a biological indicator (BI) and a chemical indicator (CI). Following the exposure to test microbial aerosol challenge, the BI's and stainless-steel coupons were aseptically transferred to culture media and incubated as required.

Following the full incubation period, negative test samples were inoculated with spores and incubated for twenty-four (24) hours per USP for growth promotion. The presence of growth verified the media could still support growth of a low number of challenge organism and that bacteriostatic substances did not inhibit growth.

- The test sample coupons demonstrated no growth following incubation of test samples.
- All positive controls were positive for growth
- All negative and environmental controls were negative for growth

Test Results

Sample ID			Aged Pouch 1	Aged Pouch 2	Unaged Pouch 3
Stainless Steel Coupon	FP0520	1	N	N	N
		BI	N	N	N
	FP2530/FP2030	1	N	N	N
		2	N	N	N
		3	N	N	N
		4	N	N	N
		5	N	N	N
		BI	N	N	N
	FP5060	1	N	N	N
		2	N	N	N
		3	N	N	N
		4	N	N	N
		5	N	N	N
		6	N	N	N
		7	N	N	N
		8	N	N	N
		9	N	N	N
		10	N	N	N
		BI	N	N	N
Environmental Control –150220-1			N	N	N
Positive Control–141020 BT 225			P	P	P
Negative Control –150220-1			N	N	N
Negative Verification–150220-1			P	P	P
Environmental Control –150203-1			N	N	N
Positive Control–RA81			P	P	P
Negative Control–150203-1			N	N	N
Negative Verification–150203-1			P	P	P

Table 2

N = Negative for growth
P = Positive for growth

Product ageing studies

STERIS has applied product ageing studies for establishing the product shelf life of STERIS sterilization reels and pouches. Data obtained from these studies are based on conditions that simulate the effects of aging on the material and its properties. STERIS product ageing studies consist of two parts: accelerated ageing and natural ageing for verification of shelf life under 'real-time' ageing conditions.

Accelerated ageing

STERIS sterilization reels and pouches have a product shelf life of 5 (five) years under recommended storage and handling conditions. Accelerated ageing study valid for 5 years has been applied according ASTM F1980 to ensure highest quality and to determine the product shelf life. Accelerated aged products have been tested for their product properties internal at STERIS laboratory.

Natural (real time) ageing

Natural ageing is essential for verification of test results obtained after accelerated ageing. STERIS sterilization reels and pouches are stored under controlled and monitored environment and product physical property tests applied in a 6, 12, 18, 24, 36, 48, and 60 monthly period.

All data resulting from the testing have been evaluated and kept under record. The test results verify the shelf life of 5 (five) years for STERIS sterilization reels and pouches under recommended storage conditions.

Cytotoxicity testing

Cytotoxicity testing is crucial to ensure biocompatibility of medical devices. This involves extracting leachable materials from the device or components and analyzing the leachable extracts for potentially harmful chemicals or cytotoxicity. STERIS sterilization reels and pouches have been tested using MEM Elution Cytotoxicity Assay per USP and ISO methods after being processed in a hospital steam sterilizer compliant to AAMI ST8 and ethylene oxide sterilizer After being exposed to steam and EO sterilization, L929 mammalian fibroblast cells samples were plated, incubated and extracted within MEM Elution fluid for 24±2 hours. Following incubation, cell culture medium was aspired, and test samples were plated in triplicate with L929 cells and incubated for 48±2 hours. Following the full incubation period, the test samples met the USP and ISO 10993-5 requirements and STERIS packaging proved its non-toxicity

STERIS sterilization packaging is non-toxic following steam and EO sterilization

Product burst test

Burst testing provides a quick means of assessing tendencies for a pouch to fail when it is exposed to a pressure differential. Pressure differentials may occur within a package during different situations, such as sterilization and transportation and it is important to ensure that the package can maintain integrity and therefore sterility throughout all reasonable circumstances. With this test, burst value of STERIS pouches is assessed per ASTM F1140.

Product packaging

The product packaging of STERIS sterilization reels and pouches consists of three packaging types: the inner packaging, the outer packaging and the transport packaging. Each packaging is done after the final product quality control by trained personnel and by use of proper selected materials to ensure protection from dust and moisture during transportation and storage.
The inner packaging of sterilization pouches is done in bundles of 250/200 or 100 pieces depending on pouch dimension and wrapped with PP film. Sterilization reels of 100 or 200 meter lengths are placed in PE bags single or in groups depending on the reel width.
For outer packaging of STERIS products, double wall corrugated cardboard boxes as shipping cartons are used. The double wall corrugated structure provides higher protection against any kind of damages during transportation and handling.

The transport packaging as the final stage prior shipment, is done by use of 4way wooden and heat treated (according ISPM-15) pallets. Proper placed shipping cartons are wrapped with PP film for protection against dust and moisture and secured with edge protections and 12m wide PET belts.

LOT number

Each STERIS sterilization reel and pouch is provided with a LOT number printed on the medical grade paper web. The LOT number allows the traceability of the product during the manufacturing process.

The LOT number is coded as following;

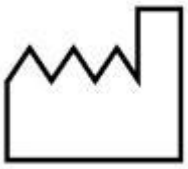
LOT WWYY

- **WW** = Week of the year
- **YY** = Year of manufacturing

The LOT number is coded as follows:
LOT WWYY
WW = Week of the year
YY = Year of manufacturing

Expiry date / shelf life

The shelf life of STERIS sterilization reels and pouches are 5 (five) years after manufacture date under recommended storage and handling conditions.
The product must be used within 5 years from date of manufacture. The expiry date, as well as the manufacture date are printed on the product traceability labels and the shipping carton label.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Expiry Date Symbol
Dd.MM.yy

Storage conditions

STERIS sterilization reels and pouches need to be stored under following recommended storage conditions to ensure optimum product quality, microbial properties and expiry date.

Storage conditions are printed on each shipping carton labels and are also available at product related instructions for use.

- Stored in original packaging
- Stored under controlled temperature (max. 35°C)
- Stored under controlled humidity (max. %70 Relative Humidity)
- Stored protected from direct sunlight, moisture and excessive airflow

Product traceability label

Each sterilization reel and pouch bundle is attached with a label including important product and manufacturing information. These labels are essential for product traceability and must be keep safe in case of any product related subjects. Each product traceability label contains following details:

- Product Item Code (Ref.)
- Lot Number
- Manufacture Date
- Expiry Date
- Machine No
- Roll / Pouch Bundle No
- Product specific barcode

Shipping carton label

Each shipping carton is attached with a label including essential product information and traceability data. Each label contains following details:

- Brand
- Product description
- Product Dimension
- Product Item Code
- Quantity
- Manufacture Date
- Expiry Date
- Lot Number
- Recommended storage conditions
- Product Barcode
- Manufacturer contact details
- CE Mark