Technical Data Monograph

STERLINK® FPS-15s Plus Sterilization System

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1. Introduction

1.1 Indication for use

The STERLINK® FPS-15s Plus sterilizer is a hydrogen peroxide gas sterilizer system intended for use in the terminal sterilization of cleaned, rinsed and dried reusable metal and nonmetal medical devices used in healthcare facilities.

The STERLINK® FPS-15s Plus sterilizer is designed for sterilization of both metal and nonmetal medical devices at low temperatures, and it can sterilize instruments which have diffusion-restricted spaces, such as the hinged portion of forceps and scissors.
Medical devices with the following material and dimensions can be processed in the STERLINK® FPS-15s Plus sterilizer:

Single channel stainless steel lumens with
- inside diameter of 0.7 mm or larger and a length of 500 mm or shorter
- inside diameter of 2.0 mm or larger and a length of 1500 mm or shorter

Single channel polytetrafluoroethylene (PTFE) lumens with
- inside diameter of 1.0 mm or larger and a length of 2000 mm or shorter

The validation testing for this lumen size was conducted using a maximum of 3, 5, and 5 lumens per load for the Pouch, Pouch Plus, and Chamber mode, respectively. It is noteworthy that hospital loads should not exceed the maximum number of lumens validated by this testing.

The sterilization load for each mode is defined as below.

Mode	Item description
Pouch	Total mass of the items should be less than 0.5 kg.
Pouch Plus	Total mass of the items should be less than 1.5 kg.
Chamber	Total mass of the items should be less than 5.0 kg.

1.2 Substantial equivalence

The STERLINK® FPS-15s Plus Sterilizer is substantially equivalent to previously marketed devices, including predicated product; the Sterilucent PSD-85 Hydrogen Peroxide Sterilizer (FDA 510(k) number of K140464) and reference product; V-PRO® 60 Low Temperature Sterilization system (FDA 510(k) number of K140498) manufactured by Sterilucent, Inc. & Streis Corporation.

The design features and sizing of the components were also compared and the STERLINK® FPS-15s Plus Sterilizer found to be substantially the same as these systems. It is made of the same FDA recognized materials and is indicated for the same intended uses as these systems. There are no significant differences between the STERLINK® FPS-15s Plus Sterilizer and other systems currently being marketed which would adversely affect the use of the product. It is substantially equivalent to these other devices in design, function, material and intended use.

4. Performance

4.1 Lumen sterilization

The biological indicators (BI) were inserted in the single-channel lumens for each as described in Table 4.1. For each test, the lumens prepared were inserted in STERPACK®, STERPACK® Plus or Tyvek® with dried validation loads for each mode and sealed together as expressed in Table 4.2. The prepared pouch was processed with half cycle sterilization of pouch mode, pouch plus mode or chamber mode. After sterilization cycle, the BIs were immediately removed from the lumens. The internal ampoules of BIs were broken and shaken sufficiently so that the media be spread uniformly. All the BIs processed and positive control were incubated at 60ºC for 72 hours and were inspected. The results were reported as positive (yellow) or negative (purple). The lumen sterilization tests except positive control were performed in three consecutive half sterilization cycles. The results are described in Table 4.3.

Table 4.1 Lumen types for the test

Lumen type	Diameter [mm]	Length [mm]
L1: Single-channel stainless steel lumen	0.7	500
L2: Single-channel stainless steel lumen	2.0	1500
L3: Polytetrafluoroethylene (PTFE) lumen	1.0	2000

Table 4.2 Validation loads for the test

Mode	# of the lumens	Total weight of validation loads [lbs]
Pouch (STERPACK®)	3	0.36 (2 handpieces)
Pouch Plus (STERPACK® Plus)	5	0.90 (5 handpieces)
Chamber (Tyvek®)	5	3.47 (Tyvek® pouch-sealed aluminum materials)

Table 4.3 Results of lumen sterilization test

Mode	Test	Number of positive/Number of tested		
		#1	#2	#3
Pouch	Positive control		1/1	
	L1 - 3 repetitive tests	0/3	0/3	0/3
	L2 - 3 repetitive tests	0/3	0/3	0/3
	L3 - 3 repetitive tests	0/3	0/3	0/3
Pouch Plus	Positive control		1/1	
	L1 - 3 repetitive tests	0/5	0/5	0/5
	L2 - 3 repetitive tests	0/5	0/5	0/5
	L3 - 3 repetitive tests	0/5	0/5	0/5
Chamber	Positive control		1/1	
	L1 - 3 repetitive tests	0/5	0/5	0/5

	L2 - 3 repetitive tests	0/5	0/5	0/5
	L3 - 3 repetitive tests	0/5	0/5	0/5

Conclusion: The results of three consecutive lumen sterilization tests were shown as all negative except positive controls. According to the test results, lumen sterilization test is completely successful.

4.2 Surface sterilization

Seven stainless-steel and PTFE coupons were prepared for each as spore carriers as explained in Table 4.4. *G. stearothermophilus* spore suspension of 0.1 ml were inoculated on each coupon surface, and dried. For each test, the five carriers prepared were inserted in STERPACK®, STERPACK® Plus or Tyvek® with dried validation loads for each mode and sealed together as described in Table 4.5. The prepared pouch was processed with half cycle sterilization of pouch mode, pouch plus mode or chamber mode. Two carriers were left on the room temperature without sterilization process as positive control samples in Table 4.6. After sterilization cycle, the inoculated area on carriers were rubbed by swab sterilized and moistened with tryptic soy broth. This process was repeated using a new swab twice for each. The swab heads were cut by a flame-sterilized scissor and placed in the tryptic soy broth of 5 ml. All samples were incubated at 58ºC for 7 days. After incubation, all samples were mixed by a vortex mixer and the turbidity change of media was inspected. The results were reported as positive (growth) or negative (no growth). The surface sterilization tests except positive control were performed in three consecutive half sterilization cycles. The results are stated in Table 4.7.

Table 4.4 Coupons for the test

Type	Dimension in W × L × H [mm]	Material
Stainless-steel coupon	20 × 50 × 1	Stainless-steel (SUS 304)
PTFE coupon	20 × 50 × 1	Polytetrafluoroethylene (PTFE)

Table 4.5 Validation loads for the test

Mode	# of the carriers	Total weight of validation loads [lbs]
Pouch (STERPACK®)	5	1.08 (6 handpieces)
Pouch Plus (STERPACK® Plus)	5	3.91 (Aluminum blocks)
Chamber (Tyvek®)	5	7.05 (Tyvek® pouch-sealed aluminum materials)

Table 4.6 The number of recovered spores from the coupons (positive control)

Type	Number of recovered spores [× 10^6 CFU]	
	#1	#2
Stainless-steel coupon	1.69 ± 0.06	1.65 ± 0.03
PTFE coupon	1.55± 0.07	1.63 ± 0.06

Table 4.7 Results of surface sterilization test

Mode	Test	Number of positive/Number of tested					
		Stainless-steel coupon			PTFE coupon		
Pouch	Positive control	2/2			2/2		
	3 repetitive tests	0/5	0/5	0/5	0/5	0/5	0/5
Pouch Plus	Positive control	2/2			2/2		
	3 repetitive tests	0/5	0/5	0/5	0/5	0/5	0/5
Chamber	Positive control	2/2			2/2		
	3 repetitive tests	0/5	0/5	0/5	0/5	0/5	0/5

Conclusion: The spores from coupon for each test were recovered as above 1.0 × 10^6 CFU. The results of three consecutive surface sterilization tests were shown as all negative except positive controls. According to the test results, the surface sterilization test is completely successful.

4.3 Mated surface sterilization

Seven stainless-steel scissors and PTFE coupons were prepared for each as spore carriers as described in Table 4.8. *G. stearothermophilus* spore suspension of 0.1 ml were inoculated on each surface of scissor and coupon to be mated, and dried. After dried, the blades of scissors were overlapped, and the coupons were stacked with another coupon to make the inoculated surface covered. Both sides of stacked coupons were tied by using PTFE tape. For each test, the five carriers prepared were inserted in STERPACK®, STERPACK® Plus or Tyvek® with dried validation loads for each mode and sealed together as explained in Table 4.9. The prepared pouch was processed with half cycle sterilization of pouch mode, pouch plus mode or chamber mode. Two carriers were left on the room temperature without sterilization process as positive control samples in Table 4.10. After sterilization cycle, the inoculated area on carriers were rubbed by swab sterilized and moistened with tryptic soy broth. This process was repeated using a new swab twice for each. The swab heads were cut by a flame-sterilized scissor and placed in the tryptic soy broth of 5 ml. All samples were incubated at 58ºC for 7 days. After incubation, all samples were mixed by a vortex mixer and the turbidity change of media was inspected. The results were reported as positive (growth) or negative (no growth). The mated surface sterilization tests except positive control were performed in three consecutive half sterilization cycles. The results are expressed in Table 4.11.

Table 4.8 Carriers for the test

Type	Dimension [mm]	Material
Scissor (Kasco/S5-033)	140 (in L)	Stainless-steel (SUS 304)
Coupon	20 × 50 × 5 (in W × L × H)	Polytetrafluoroethylene (PTFE)

Table 4.9 Validation loads for the test

Mode	# of the carriers	Total weight of validation loads [lbs]
Pouch (STERPACK®)	5	1.08 (6 handpieces)
Pouch Plus (STERPACK® Plus)	5	3.91 (Aluminum blocks)
Chamber (Tyvek®)	5	7.05 (Tyvek® pouch-sealed aluminum materials)

Table 4.10 The number of recovered spores from the carriers (positive control)

Type	Number of recovered spores [× 10^6 CFU]	
	#1	#2
Scissor	1.78 ± 0.02	1.55 ± 0.04
PTFE coupon	1.88 ± 0.04	1.84 ± 0.01

Table 4.11 Results of surface sterilization test

Mode	Test	Number of positive/Number of tested					
		Stainless-steel scissor			PTFE coupon		
Pouch	Positive control	2/2			2/2		
	3 repetitive tests	0/5	0/5	0/5	0/5	0/5	0/5
Pouch Plus	Positive control	2/2			2/2		
	3 repetitive tests	0/5	0/5	0/5	0/5	0/5	0/5
Chamber	Positive control	2/2			2/2		
	3 repetitive tests	0/5	0/5	0/5	0/5	0/5	0/5

Conclusion: The spores from carrier for each test were recovered as above 1.0 × 10^6 CFU. The results of three consecutive mated surface sterilization tests were shown as all negative except positive controls. According to the test results, the mated surface sterilization test is completely successful.

4.4 Endoscope test

Three stainless-steel wire were cut into the length of 600 mm for each as spore carriers as explained in Table 4.12. *G. stearothermophilus* spore suspension was inoculated on one end of each stainless-steel wire, and dried. After dried, the stainless-steel wire was inserted in flexible endoscope as the inoculated position was placed in the middle of the endoscope in Table 4.13. The prepared endoscope was inserted in Tyvek® and sealed. The prepared pouch was processed with half cycle sterilization of chamber mode. Two carriers were left on the room temperature without sterilization process as positive control samples

in Table 4.14. After sterilization cycle, the inoculated position on carriers were cut by a flame-sterilized scissor and placed in the tryptic soy broth of 5 ml. All samples were incubated at 58ºC for 7 days. After incubation, all samples were mixed by a vortex mixer and the turbidity change of media was inspected. The results were reported as positive (growth) or negative (no growth). The endoscope sterilization tests except positive control were performed in three consecutive half sterilization cycle. The results are described in Table 4.15.

Table 4.12 Specification of stainless-steel wire carrier

Item	Details
Model	HW-308
Brand	WAKISANGYO
Dimension	Diameter: 0.29-0.30 mm, Length: 20 m
Material	Stainless-steel (SUS 304)

Table 4.13 Specification of endoscope

Item	Details
Model	EG-2700
Brand	Pentax®
Category	Video Gastroscopes
Dimension	Biopsy Channel Size: 2.2 mm, Working Length: 1,050 mm, Total Length: 1,370 mm

Table 4.14 The number of recovered spores from the carrier (positive control)

Try	Number of recovered spores [× 10^6 CFU]
#1	1.91 ± 0.01
#2	1.67 ± 0.01

Table 4.15 Results of endoscope sterilization test

Mode	Test	Number of positive/Number of tested		
Chamber	Positive control	2/2		
	3 repetitive tests	0/1	0/1	0/1

Conclusion: The spores from carrier for each test were recovered as above 1.0 × 10^6 CFU. The results of three consecutive endoscope sterilization tests were shown as all negative except positive control. According to the test results, the endoscope sterilization test is completely successful.

4.5 Simulated-use test

G. stearothermophilus spore suspension of 0.1 ml was centrifuged for 2 minutes at 13,500 rpm. After the centrifugation, the supernatant was discarded, and the pellet was mixed with 0.1 ml hard water of 300 ppm containing 5% fetal bovine serum. The prepared spore suspension was inoculated on specified area of the instruments listed on the Table 4.16 and dried. After dried, the inoculated instruments were inserted in STERPACK®, STERPACK® Plus or Tyvek® and sealed. The prepared pouch was processed with full cycle sterilization of pouch mode, pouch plus mode or chamber mode. After the sterilization process, the survivor spores of the instruments were recovered by following methods.

- Dental surgical kit
The inoculated component was put in elution recovery fluid of 0.1% triton X-100 with total amount of 10 ml solution. The recovered solution was mixed using a vortex mixer for 7 minutes.

- Scissors and external surface of the endoscope
The inoculated spore was rubbed by a swab which sterilized and moistened with elution recovery fluid. This process was repeated using a new swab twice for each. The swab heads were cut by a flame-sterilized scissor and placed in the elution recovery fluid of 10 ml. The tubes containing the recovery fluid were mixed using a vortex mixer for 7 minutes to recover the spores from the swabs.

- Internal endoscope
The whole area inside was irrigated aseptically with elution recovery fluid of 30 ml to recover the spores inoculated inside the endoscope.

The elution recovery fluid containing recovered spores were diluted by serial 10-fold dilution method to 10^{-2}. This process was repeated three times. Each 10^{-1} and 10^{-2} dilution samples were divided in half and inoculated in tryptic soy agar by pour plating method. The inoculated plates were incubated at 58ºC for 48 hours. After incubation, exist of the spores that survived from sterilized cycle were determined by checking CFU on tryptic soy agar. All the tests were performed with five replicates. The results are stated in Table 4.18.

Table 4.16 Instruments for the test

Mode	Instrument	Brand / Model	Inoculated area
Pouch	Scissor	Kasco / S5-03	Mated surface
Pouch Plus	Dental surgical kit	Warantec / SMS-K200	Surface of implant kit
Chamber	Endoscope (Video Gastroscopes)	Pentax® / EG-2700	External surface
			Internal area

Table 4.17 The number of recovered spores from control samples (positive control)

Instrument	Inoculated area	Number of recovered spores [× 10^6 CFU]	
		#1	#2
Scissor	Mated surface	1.57 ± 0.04	1.51 ± 0.06
Dental surgical kit	Surface	1.55 ± 0.06	2.10 ± 0.24
Endoscope	External surface	1.97 ± 0.13	1.96 ± 0.03
	Internal surface	1.94 ± 0.05	1.60 ± 0.10

Table 4.18 The number of recovered spores from the test samples

Mode	Instrument	Test number	Number of recovered spores
Pouch	Scissor	1	Not detected
		2	Not detected
		3	Not detected
		4	Not detected
		5	Not detected
Pouch Plus	Dental surgical kit	1	Not detected
		2	Not detected
		3	Not detected
		4	Not detected
Chamber	Endoscope (external)	1	Not detected
		2	Not detected
		3	Not detected
		4	Not detected
		5	Not detected
	Endoscope (internal)	1	Not detected
		2	Not detected
		3	Not detected
		4	Not detected
		5	Not detected

Conclusion: The spores from control sample for each test were recovered as above 1.0 × 10^6 CFU. The colony of recover fluid from all test samples for each test were non-detected. According to the test results, the simulated-use test is completely successful.

4.6 In-use test

Tests for all modes were proceeded in a clinic or hospital using the test instruments that used in routine examination on the field. The test instruments were cleaned and dried in the clinic or hospital. The cleaned instruments were inserted in STERPACK®, STERPACK® Plus or Tyvek® according to the Table 4.19. The prepared pouch was processed with full cycle sterilization of pouch mode, pouch plus

mode, or chamber mode. After the sterilization process, the instruments were delivered to the laboratory and the survivor bacteria were recovered by same method of simulated-use test. The elution recovery fluid containing recovered bacteria were diluted by serial 10-fold dilution method to 10-1. This process was repeated for three times. The dilution samples of 10-1 were divided into half and inoculated in tryptic soy agar by pour plating method. The inoculated plates were incubated at 37ºC for 48 hours. After incubation, existence of the bacteria that survived from sterilized cycle were determined by checking the grown colony on tryptic soy agar. All the tests were performed with three replicates, and the results are described in Table 4.21.

Table 4.19 Instruments for the test

Mode	Instrument
Pouch (STERPACK®)	Dental mirror, dental pincette, and suction tip
Pouch Plus (STERPACK® Plus)	Esophagogastroduodenoscopy (EGD) biopsy forceps
Chamber (Tyvek®)	Gastroscope

Table 4.20 The number of recovered bacteria from the control samples (positive control)

Instrument	Number of recovered bacteria [CFU]	
	#1	#2
Suction tip	$(5.5 \pm 0.25) \times 10^2$	$(1.1 \pm 0.09) \times 10^3$
EGD biopsy forceps	$(5.7 \pm 1.56) \times 10^2$	$(3.6 \pm 0.33) \times 10^2$
Gastroscope	$(1.3 \pm 0.08) \times 10^4$	$(1.9 \pm 0.06) \times 10^4$

Table 4.21 The number of recovered bacteria from the test samples

Mode	Instrument	Test number	Number of recovered bacteria
Pouch	Suction tip	1	Not detected
		2	Not detected
		3	Not detected
Pouch Plus	EGD biopsy forceps	1	Not detected
		2	Not detected
		3	Not detected
Chamber	Gastroscope	1	Not detected
		2	Not detected
		3	Not detected

Conclusion: The colony was non-detected in the recovered fluid from all test samples after each sterilization mode. According to the test results, the in-use test is completely successful.

4.7 Sporicidal activity test

For the test, 60 carriers of suture loops and cylinders inoculated with *B. subtilis* and *C. sporogenes*, were inserted in STERPACK® and sealed. The prepared pouch was processed with a full cycle sterilization of pouch mode. After the sterilization cycle, each carrier was transferred to primary subculture tubes containing fluid thioglycolate medium (FTM) of 10 ml as a neutralizer in sequentially at 2 minutes intervals. After each carrier was deposited, the test tube with carrier was gently shaken and the carrier of primary tubes was transferred to secondary subculture tubes containing FTM of 10 ml as recovery medium with the interval time of 2 minutes per one carrier. After all carriers had been transferred, entire test tubes were gently shaken. For positive controls, one of the inoculated carriers was transferred to secondary subculture tube. For media sterility controls, one of unopened subculture tubes with FTM of 10 ml were used. For system controls (checking for aseptic technique during carrier transfer process), three sterile carriers were inserted in STERPACK® and sealed. The prepared pouch was processed with a full cycle sterilization of pouch mode. After the sterilization cycle, carriers were transferred to FTM medium of 10 ml twice, according to the standards. All tubes including test and control tubes were incubated at 37ºC for 21days. After the incubation, all samples were shaken, and the turbidity changes of the media were inspected. The results were determined by the turbidity in the samples; the turbid is positive and the clear is negative. The primary and secondary subculture tubes for each carrier represent the carrier sets. The positive result in either primary or secondary subculture tube is considered as a positive result for the carrier set. If no growth had been observed after 21 days, the subculture tubes were treated by heat-shock for 20 minutes at 80ºC and incubated for 72 hours at 37ºC more. After the second incubation, the results were reported as positive or negative. Efficacy tests of the disinfectants were performed in triplicate. The results are described in Table 4.23.

Table 4.22 The average number of recovered spores from the five carriers (positive control)

Species	Carrier	Number of recovered spores [× 10^6 CFU]
B. subtilis	Cylinder	1.40 ± 0.14
	Suture loop	1.73 ± 0.03
C. sporogenes	Cylinder	1.20 ± 0.09
	Suture loop	1.55 ± 0.04

Table 4.23 Results of the efficacy test

Species	Carrier	Condition	Number of positive set/Number of tested set		
			#1	#2	#3
B. subtilis	Cylinder	Positive control	1/1	1/1	1/1
		Media sterility control	0/1	0/1	0/1

		System controls	0/3	0/3	0/3
		Tests	0/60	0/60	0/60
	Suture loop	Positive control	1/1	1/1	1/1
		Media sterility control	0/1	0/1	0/1
		System controls	0/3	0/3	0/3
		Tests	0/60	0/60	0/60
C. sporogenes	Cylinder	Positive control	1/1	1/1	1/1
		Media sterility control	0/1	0/1	0/1
		System controls	0/3	0/3	0/3
		Tests	0/60	0/60	0/60
	Suture loop	Positive control	1/1	1/1	1/1
		Media sterility control	0/1	0/1	0/1
		System controls	0/3	0/3	0/3
		Tests	0/60	0/60	0/60

Conclusion: The number of spores from carrier for each test were recovered as above 1.0 × 10^6 CFU. The spores of inoculated carrier were resistant to HCl exposure for more than 2 minutes. The results of three efficacy tests, all the test samples were shown as all negative. According to the test results, the sporicidal activity test is completely successful.