TEST·INSPECTION REPORT

Biocompatibility Test

Manufacturer Name: Plasmapp Co., Ltd.

Representative: Youbong, LIM

Location: BVC-111, 125, Gwahak-ro, Yuseong-gu, Daejeon, 34141, Republic of Korea

Product Name: Low temperature plasma sterilizer and sterilant

Brand Name: STERLINK® and STERMATE®

Model Name: FPS-15s Plus (FPS-15s^{+}) and STERLOAD®

Serial/Lot Number: P15BTM023A, SL19F001, and SL19K001

Test·Inspection Item: Biocompatibility Test

Testing Laboratory:

Korea Testing and Research Institute KTR 한국화학융합시험연구원 KOREA TESTING & RESEARCH INSTITUTE
12-63, Sandan-gil, Hwasun-eup, Hwasun-gun, Jeollanam-do, 58141, Republic of Korea

Decision: Pass

Plasmapp Research Institute

Biocompatibility Test

1. Test schedule

1.1 Date of test beginning: 21 Jun. 2019

1.2 Date of test completion: 04 Feb. 2020

2. Test article

Low temperature plasma sterilizer (STERLINK® FPS-15s Plus, S/N: P15BTM023A)

Sterilant (STERLOAD®, Lot No.: SL19F001and SL19K001)

3. Test guideline

3.1 The tests were performed according to the ISO 10993-5 standard in compliance with the principles of Good Laboratory Practice (GLP).

3.2 Information of testing materials

3.2.1 Coupons

Material	Dimensions [mm]	Manufacturer/Model
Aluminum (Al 5052)	20 × 50 × 1 in W × L × T	-
Aluminum (Al 6061)	20 × 50 × 2 in W × L × T	-
Stainless steel (SUS 316L)	20 × 50 × 1 in W × L × T	-
Stainless steel (SUS 304)	20 × 50 × 1 in W × L × T	-
Titanium	20 × 50 × 1 in W × L × T	-
High density polyethylene (HDPE)	20 × 50 × 1 in W × L × T	-
Polypropylene (PP)	20 × 50 × 2 in W × L × T	-
Polytetrafluoroethylene (PTFE)	20 × 50 × 1 in W × L × T	-
Acrylonitrile butadiene styrene (ABS)	20 × 35 × 2 in W × L × T	-
Silicone	4.78 × 7.95 × 30 in I.D. × O.D. × L	NewAge Industries, Inc. / APST-0188-0313L
Tyvek®	20 × 50 in W × L	Sigma Medical Supplies Corp. / TYFR150070

3.2.2 Sterilant

Brand	STERMATE®	
Model	STERLOAD®	
Lot Number	SL19F001	SL19K001
Expiration date	May 2020	Nov. 2020
Manufacturer	Plasmapp Co., Ltd.	
Comments	Sterilant cassette for STERLINK®	

3.2.3 Measuring instrument

Equipment	**Manufacturer**	**Model**	**Internal S/N**	**Calibration date**
High temperature data logger	MADGETECH	HiTemp140	PQ-C-032	14 Aug. 2018
High temperature data logger	MADGETECH	HiTemp140	PO-C-027	27 Sep. 2019
Pressure data logger	MADGETECH	PR140	PQ-C-031	13 Aug. 2018
Pressure data logger	MADGETECH	PR140	PO-C-018	02 Apr. 2019

3.3 Test methods

In order to confirm the biological safety of the sterilized objects by STERLINK® FPS-15s Plus, after full cycle of chamber mode, the cytotoxicity test was performed for the sterilized various material coupons. **For the worst-case condition, the coupons were sterilized in three consecutive full cycle of chamber mode.** The temperature and pressure during the sterilization process were measured.

4. Test results**

4.1 Results of biocompatibility test

The results of cytotoxicity test, the eleven types of samples sterilized by three consecutive full cycle of chamber mode were shown no evidence of cell lysis or toxicity.
The cytotoxicity test results for sterilized each material coupon were attached as a test report with the following name.

Material	Test number (Test schedule)	Test report
Aluminum (Al 5052)	Test 1 (21 Jun. 2019 - 07 Aug. 2019)	C_Al5052
Aluminum (Al 6061)		C_Al 6061
Stainless steel (SS 316L)		C_SS316L
Stainless steel (SS 304)		C_SS304
Titanium		C_Ti
High density polyethylene (HDPE)		C_HDPE
Polypropylene (PP)		C_PP
Polytetrafluoroethylene (PTFE)		C_PTFE
Acrylonitrile butadiene styrene (ABS)	Test 2 (05 Dec. 2019 -04 Feb. 2020)	C_ABS
Silicone		C_Silicone
Tyvek®		C_Tyvek

4.2. Pressure parameter data during sterilization process [Torr]

Test number	Cycle number	1st sterilant injection		2nd sterilant injection		Purification
		Base[a] (< 3 Torr)	Diffusion[b] (20 - 100 Torr)	Base[a] (< 3 Torr)	Diffusion[b] (20 - 100 Torr)	Final base[c] (< 3 Torr)
1	1	0.1	42.6	0.3	40.9	0.2
	2	0.2	41.7	0.3	40.6	0.2
	3	0.01	41.8	0.2	41.2	0.4
2	1	0.08	40.6	0.2	42.1	0.08
	2	0.02	39.0	0.02	40.4	0.05
	3	0.02	40.2	0.05	39.1	0.02

**The time evolution of pressures and temperature inside the chamber during the sterilization process were described in the Appendix 1.
[a]The base pressure just before injection of the sterilant.
[b]The diffusion pressure after diffusion of the sterilant which is complete.
[c]The base pressure after injection and purification.

4.3. Temperature parameter data during sterilization process [°C]

Test number	Cycle number	Sterilization phase 1			Sterilization phase 2		
		Load[d] (50-60°C)	Chamber[e] (55-60°C)	Vaporizer[f] (110-130°C)	Load[d] (50-60°C)	Chamber[e] (55-60°C)	Vaporizer[f] (110-130°C)
1	1	53.0 - 57.5	55.3 - 56.6	115 - 125	53.7 - 58.1	55.2 - 56.6	116 - 125
	2	53.6 - 58.7	55.4 - 56.7	114 - 127	54.1 - 59.1	55.3 - 56.4	113 - 124
	3	53.1 - 57.6	55.4 - 56.6	116 - 126	53.5 - 58.2	55.5 - 56.3	114 - 126
2	1	54.3 - 59.2	55.2 - 56.8	115 - 123	54.3 - 59.0	55.3 - 56.5	113 - 126
	2	54.3 - 59.2	55.6 - 56.4	113 - 124	54.3 - 59.0	55.6 - 56.6	115 - 124
	3	53.1 - 57.4	55.5 - 56.6	117 - 125	53.7 - 57.9	55.4 - 56.7	115 - 122

4.4. Time parameter data during sterilization process [s]

Test number	Cycle number	Sterilization phase 1 (450 ± 1 s)	Sterilization phase 2 (450 ± 1 s)
1	1	450	450
	2	450	450
	3	450	450
2	1	450	450
	2	450	450
	3	450	450

5. Conclusions

(1) The result of the cytotoxicity test, all test samples were noncytotoxic and evaluated grade 0 under the ISO 10993-5 standard despite being exposed to three consecutive full cycle sterilization.

(2) According to the test results, the residues on the eleven material coupons after sterilized with chamber mode of STERLINK® FPS-15s Plus was not affected to viable cells.

[d]The load temperature is measured by the temperature data logger described in 3.2.3.
[e]The chamber temperature is controlled by K-type thermocouple.
[f]The vaporizer temperature is controlled by K-type thermocouple.

Appendix 1

1. Pressure and temperature curves of the biocompatibility test

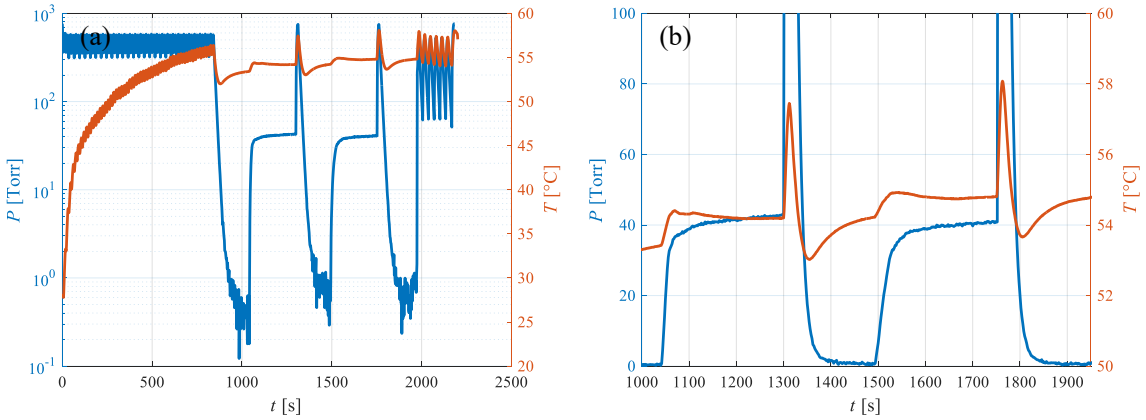

Figure 4.1 (a) The whole plot of pressure and temperature curve during the full cycle and (b) magnified plot of diffusion phase for 1st full cycle of test 1.

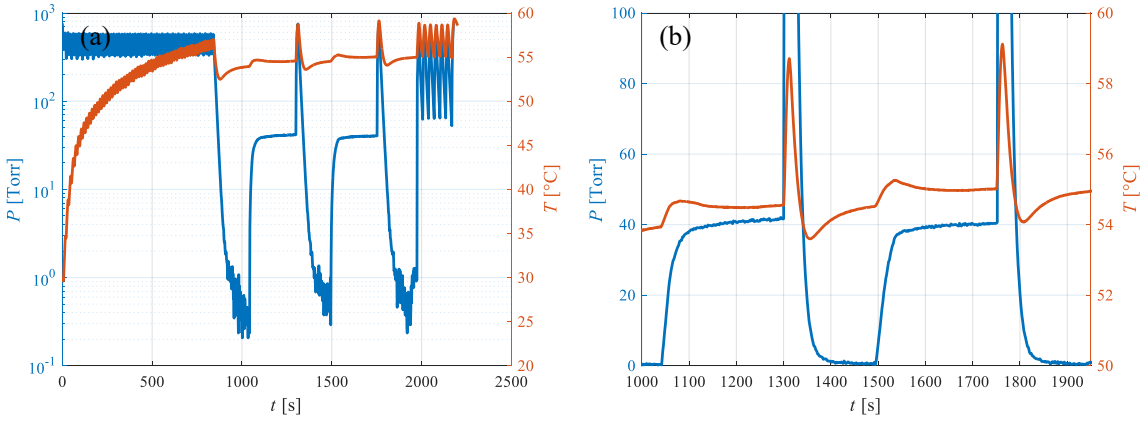

Figure 4.2 (a) The whole plot of pressure and temperature curve during the full cycle and (b) magnified plot of diffusion phase for 2nd full cycle of test 1.

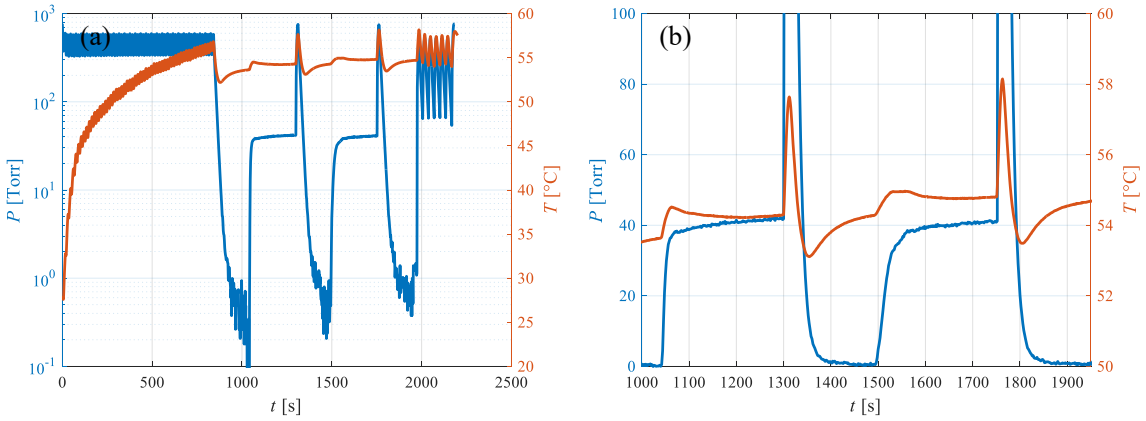

Figure 4.3 (a) The whole plot of pressure and temperature curve during the full cycle and (b) magnified plot of diffusion phase for 3rd full cycle of test 1.

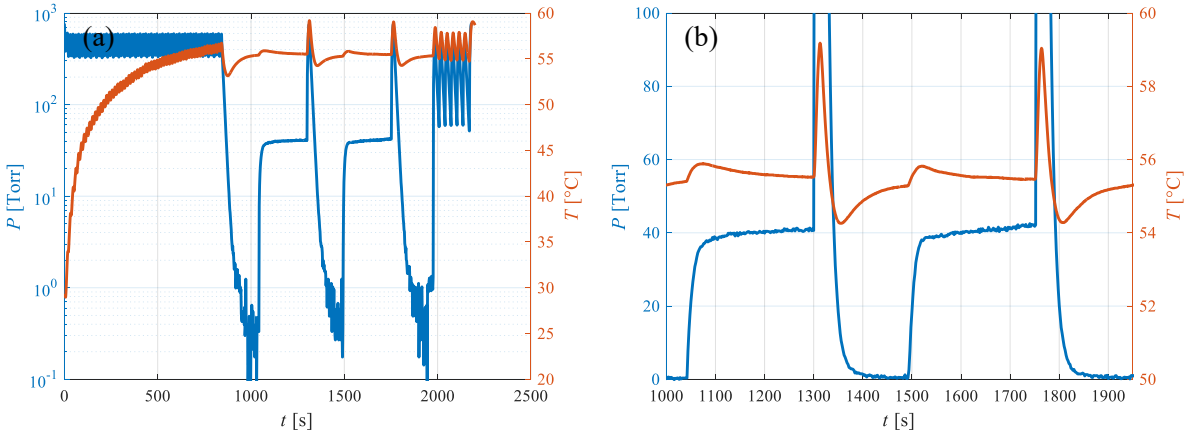

Figure 4.4 (a) The whole plot of pressure and temperature curve during the full cycle and (b) magnified plot of diffusion phase for 1st full cycle of test 2.

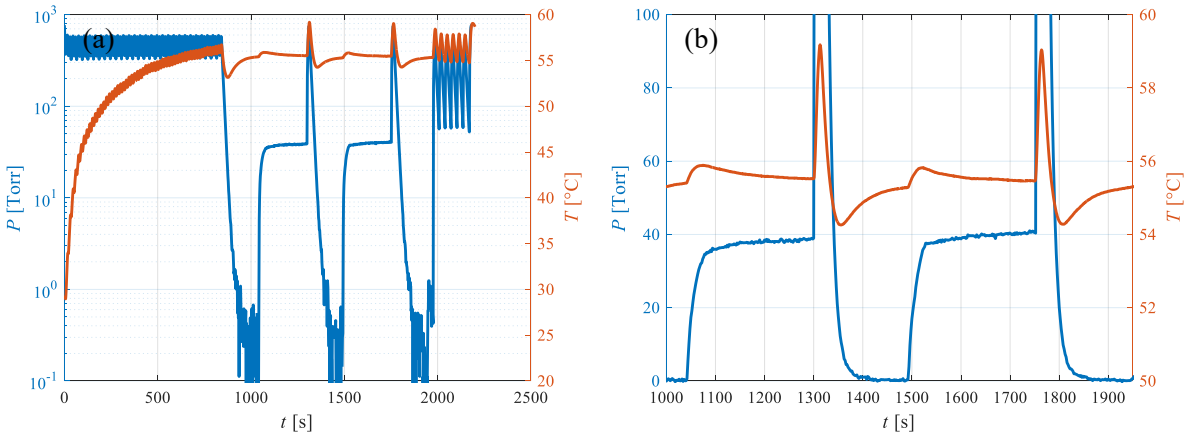

Figure 4.5 (a) The whole plot of pressure and temperature curve during the full cycle and (b) magnified plot of diffusion phase for 2nd full cycle of test 2.

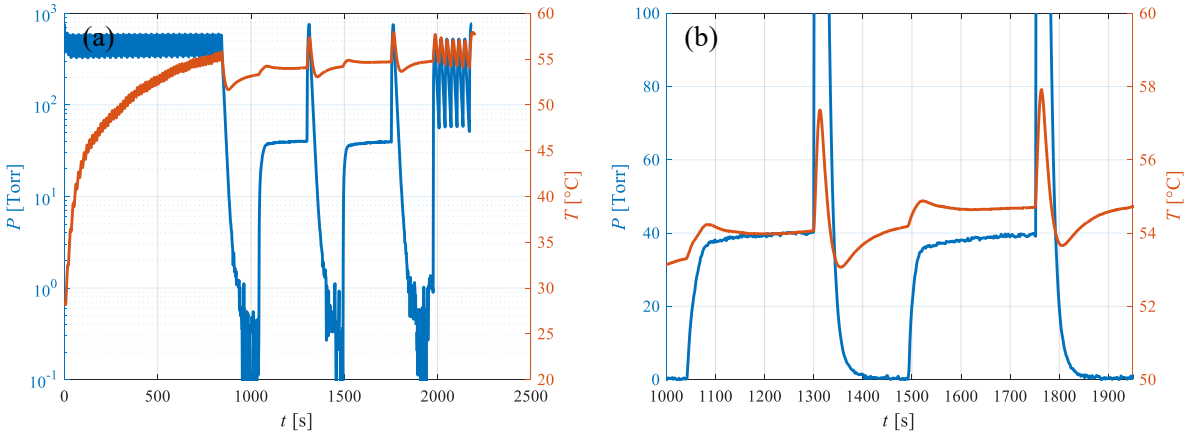

Figure 4.6 (a) The whole plot of pressure and temperature curve during the full cycle and (b) magnified plot of diffusion phase for 3rd full cycle of test 2.