REPORT OF ANALYSIS

CLIENT 12866

REPORT DATE: 4/4/13

Sam Wainer
Horizons Imaging Systems Groups
18531 S. Miles Rd.
Cleveland, OH 44128

REPORT NUMBER: 12L0354S-M01

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SAMPLE IDENTIFICATION

Name: Metalphoto Photosensitive Anodized Aluminum
Physical Description: Metalphoto Photosensitive Anodized Aluminum Nameplates, Labels and Panel Fronts
Total Quantity Received for Testing: 16
Storage Condition: Room Temperature
Date Received: 12/21/12

STEAM STERILIZATION VALIDATION

1. INTRODUCTION

1.1. To perform product qualification for Steam Sterilization as a process used to sterilize *Metalphoto Photosensitive Anodized Aluminum* submitted by Horizons Imaging Systems Group, an "Overkill" approach method was used to achieve a Sterility Assurance Level of 10^6. Sterility Assurance Level (SAL) is the probability of an item being non-sterile after it has been exposed to a validated sterilization process. Most medical devices are sterilized to achieve a SAL of 10^{-6}, which is the probability of one chance in a million that a single viable microorganism is present on a sterilized item.

1.2. Three consecutive one-half sterilization cycles was used in order to measure a 12 log microbial reduction that will provide a 10^{-6} probability of microbial survival (SAL). Sterility of items with an initial population of 10^6 after one-half sterilization can be extrapolated to a minimum twelve (12) log reductions after the full exposure. The half-cycle exposures should result in the total inactivation of the biological indicators with a population of not less than 10^6 CFU to confirm the minimum exposure time. The specified exposure time should be at least double the minimum time used to inactivate the biological indicators used.

1.3. Studies such as this typically utilize spores of *Geobacillus stearothermophilus* to serve as the microbial challenge. This organism was chosen based on its resistance to moist heat sterilization, which should provide a worst case over naturally occurring product bioburden organisms. The sterilization validation was performed in triplicate to demonstrate that the process is reproducible.

2. OBJECTIVE

2.1. To qualify steam sterilization as a method to sterilize *Metalphoto Photosensitive Anodized Aluminum* to achieve a sterility assurance level (SAL) of 10^{-6}.

3. SCOPE

3.1. This report details a sterilization validation via sample preparation with microbial challenge, steam sterilization exposures and sterility testing (audit). Three consecutive cycles was performed and after each cycle, sterility test will be conducted to determine the efficacy of the procedure to provide sterility assurance after exposure using the defined parameters. Bacteriostasis and Fungistasis (B&F) was performed initially before initiating the actual steam exposure to validate the procedure to be used for sterility testing.

4. REFERENCES

4.1. PBL SOP 13A-01, Rev. 2F.04 *Preparation and maintenance of Microorganisms Assay Suspension*

4.2. *Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities:* FDA Reviewer Guidance, Office of Device Evaluation

4.3. PBL SOP 05B-50, Rev. 5A.02 *Operation and Maintenance of the ARS 2005 Autoclave.*

4.4. PBL SOP 14B-07, Rev. 4B.01 *General Sterility Testing – Direct Transfer.*

4.5. PBL SOP 14B-10, Rev. 7D.00 *Bacteriostasis/Fungistasis Testing – Membrane Filtration/Direct Transfer*

4.6. *Sterilization of health care products –Moist Heat- Requirements for the development, validation and routine control of sterilization process for medical devices* - ANSI/AAMI/ISO 17665-1:2006.

4.7. *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities,* ANSI/AAMI ST79:2010 & A1:2010 & A2:2011

5. MATERIALS/EQUIPMENT

5.1. Metalphoto Photosensitive Anodized Aluminum

5.2. Soybean Casein Digest Medium (SCDM)

5.3. Self-seal sterilization pouch

5.4. HEPA laminar flow hood

5.5. Autoclave, located at Pacific BioLabs

5.6. Incubator (55 – 60°C)

5.7. Test microorganism (spore suspensions)

5.7.1. *Geobacillus stearothermophilus* ATCC 7953 (formerly known as *Bacillus stearothermophilus*)

6. PROCEDURES

6.1. BACTERIOSTASIS & FUNGISTASIS (B&F)

6.1.1. This preliminary testing was performed to validate the procedure used to perform sterility testing and ensure that false negative results will not occur in the sterility tests. To make sure that the product will not exert any static effect on the microorganism growth and make modifications if necessary to cancel or remove the static effect if present.

6.1.2. This test was performed following PBL Standard Operating Procedure 14B-10, *Bacteriostasis/Fungistasis Testing – Membrane Filtration/Direct Transfer* using only one medium.

6.1.3. Three sterile devices were used to perform this test. Each of these devices were inoculated with not more than 100 CFU of the appropriate microorganism (*Geobacillus stearothermophilus*) and individually transferred directly to a sterile container with Soybean Casein Digest Medium (SCDM). Positive control utilized the same media to test the product.

6.1.4. All test products and positive control were incubated for not less than 5 days.

6.2. STEAM STERILIZATION EFFICACY TEST

6.2.1. SAMPLE PREPARATION

6.2.1.1. A total of twelve (12) clean devices were used for exposure validation. Four devices were utilized for each of the three cycles. Each of the four devices was inoculated with10^6 CFU/0.1 mL *Geobacillus stearothermophlus* suspension and allowed to dry.

6.2.1.2. All inoculated devices were packaged individually using a sterilization pouch

6.2.2. AUTOCLAVE STERILIZATION INSTRUCTIONS

6.2.2.1. Three inoculated samples (test samples) prepared in section 6.2.1 were subjected to the sterilization process. The remaining inoculated sample was not be exposed to the sterilization process and served as the positive control. The test samples were positioned at the bottom shelf of the autoclave near the drain which represents the coldest area in the chamber.

6.2.2.2. The test samples were processed using the following parameters recommended in AAMI ST79:

Sterilizer Type	Temperature	Device Packaging	Half Cycle Time	Dry Time
Pre-Vacuum Cycle	132°C - 134°C	Sterilization pouch	2 minutes (Full cycle=4 min.)	20 minutes

6.2.2.3. The process was repeated for the remaining 2 cycles. A total of three consecutive half cycles were performed to complete the validation and to prove that the process is reproducible.

6.2.2.4. Prior to initiating the sterility test, the autoclave cycle was verified as within the specified parameters from the autoclave printout.

6.2.2.5. The cycle parameters were within the defined specifications hence sterility testing on the inoculated test samples was performed as per section 6.2.3., "Sterility Testing".

6.2.3. Sterility Testing

6.2.3.1. At the conclusion of each sterilization (autoclave) cycle the samples were moved aseptically into a HEPA laminar flow hood

6.2.3.2. Sterility testing was performed in an environmentally controlled room according to current Pacific Biolabs SOP 14B-07 Rev. 4B.01, General Sterility Testing-Direct Transfer.

6.2.3.3. Working within a laminar flow hood and using aseptic technique, the test articles were transferred in a sterile container with SCDM.

6.2.3.4. In a separate hood the positive control were transferred to a container with SCDM after the transfer of the entire autoclaved test samples were completed.

6.2.3.5. All the test samples and positive control were incubated at 55°C – 60°C for a minimum of 7 days.

6.2.3.6. Samples were examined for growth everyday on to the end of the incubation period. Any growth observed was recorded.

7. RESULTS

7.1. BACTERIOSTASIS AND FUNGISTASIS TEST - DIRECT TRANSFER

Test Microorganisms *Geobacillus stearothermophilus* ATCC 7953	**Sample container SCDM**	**Control container SCDM**
Device #1	Positive	Positive
Device #2	Positive	Positive
Device #3	Positive	Positive

7.1.1. Interpretation

The results of this test indicate that the test sample does not exert a gross bacteriostatic/fungistatic effect on the above microorganism used under the defined test parameters.

7.2. STEAM STERILIZATION EXPOSURE - STERILITY TEST

Pre-Vacuum cycle @ 132°C-134°C for 2 minutes half cycle, 20 min. dry time			
Cycles	**Incubation time**	**Growth**	**No growth**
Half Cycle #1 (3 devices used)	7 days	0	3
Positive Control #1	7 days	1	0
Half Cycle # 2 (3 devices used)	7 days	0	3
Positive Control #2	7 days	1	0
Half Cycle # 3 (3 devices used)	7 days	0	3
Positive Control #3	7 days	1	0

8. CONCLUSION

All three positive controls tested positive, and contained the characteristic growth of *Geobacillus stearothermophilus*.

No growth of the biological indicators in the autoclaved samples from the 3 cycle runs was observed for the 2 minute Pre-Vacuum Cycle at 132°C - 134°C.

The verified half-cycle time indicates that a full Pre-Vacuum Cycle of not less than 4 minutes at 132°C - 134°C with a 20 minute dry time is capable of a 12-log reduction, and will provide a 10^{-6} sterility assurance level of a worst-case population.

PACIFIC BIOLABS

Ma. Melanie Palmes 04/04/13
Quality Review

4/4/13
Maria Samillano, Team Leader - Medical Devices
Microbiology Services

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