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TEST REPORT
134°C PRE-VACUUM STEAM STERILIZATION VALIDATION
SURGICAL INSTRUMENTS SET

CLIENT: Buxton BioMedical, Inc.
11 Melanie Lane, Unit 8
East Hanover, NJ 07936

TEST#: 20-0152 BUX

DATE: 02/24/20

REPORT TO: Alice Schussler

TEST SYSTEM AND JUSTIFICATION:

This study evaluated the sterilization efficacy of the devices in conformance with the AAMI TIR12: *Designing, Testing, and Labeling Reusable Medical Devices For Reprocessing in Health Care Facilities: A Guide For Medical Device Manufacturers* and ANSI/AAMI/ISO 17665-1:2006/(R)2013, *Sterilization of Health Care Products – Moist Heat – Part 1: Requirements for the Development, Validation, and Routine Control of a Sterilization Process for Medical Devices*. The specific methodology is the overkill procedure described in Section 6.5 of this guidance document. Half cycles were used rather than full cycles to establish a SAL of 10^{-6}.

The validated cycle meets the cycle times recommended in ANSI/AAMI ST79:2017. The cycle validated is for wrapped devices using the pre-vacuum cycle at 134°C with a 3 minute exposure time. **The 3 minute cycle time was validated by 1.5 minute half cycles without any additional drying time using a lesser autoclave temperature of 132°C, thus providing "worst case" conditions in order to establish a Sterility Assurance Level (SAL) of 10^{-6}.** The sterilizer used for this study was the Consolidated SSR-3A that has 510k clearance (K041833) for use in healthcare facilities. SPS Medical Sporview Self-Contained Biological Indicators (BI's) were incorporated in the testing since these BI's also have 510k clearance for use in steam sterilization.

TEST ARTICLES:

(1) Buxton Orthopedic Surgical Instruments Tray, Including:

1. Carbon Fiber Blade, 30x30mm, Catalog # 52-5855-CF
2. Frazier Tube, 45°, 130x2.0mm, 6Fr, Catalog # 71-1320
3. Frazier Suction, 3F, 60°, 135mm, Catalog # 70-060-1303
4. Chisel Handle, Catalog # 24-4201
5. Arthroscopic Cup Curette, 13cm, 5°, Size 2, Catalog # 46-6205
6. Revolver Roulette Sterilizing Case & Lid, small, Catalog # 853-90-1010
7. Revolver Roulette Handle, Satin, Catalog # 853-0001
8. Revolver Roulette Handle, Ceramic finish / silicone, Catalog # 853-0004
9. Roulette Shaft, 200mm x 4mm bite, 40°, Catalog # 853-3246
10. Roulette Shaft, 200mm x 3mm bite, 40°, Catalog # 853-5236
11. Roulette Shaft, Ceramic, 300mm x 2mm bite, 40°, Catalog # 853-3928

TEST PROCEDURE:

Reference Mycoscience Protocol: "134°C Pre-Vacuum Steam Sterilization Validation Surgical Instruments Set, Protocol Rev. 01/23/20"

1) A total of (9) Biological Indicators (BI's) were used in the case for each cycle of the three sterilization validation cycles. The BI's were placed throughout the case in locations that would be considered "worst case" or more difficult to sterilize. The case was seeded with (7) BI carriers impregnated with *Geobacillus stearothermophilus* (Crosstex Spore Strip #BS-106 and Crosstex Spore Thread #THS-06) and (2) SPS Medical Sporview Self-Contained BI's. See attached protocol for BI locations.

BI Placement Justification: The BI's were placed in lumens, between mated surfaces and against thermally insulated dense regions of the instruments.

2) Two thermocouples were placed in the case and an additional thermocouple was placed in the autoclave chamber near the drain. The GE/Kaye Validator was used to monitor the cycles and provide accumulated lethality (AF_O) data.

3) The BI seeded case was wrapped in two layers of sterilization wrap as recommended in ANSI/AAMI ST79. **Bioshield sterilization wrap (#K983719) was used and the case was sterilized for 1.5 minute half cycle exposure time at a lesser temperature 132°C without any drying time in the Consolidated SSR-3A Digital Sterilizer.** After sterilization, the case was transferred to a laminar flow hood for sterility testing.

4) The BI carriers were aseptically removed from the case and transferred to individual tubes containing 10mL of Trypticase Soy Broth (TSB). The ampule of each of the SporView BI's was crushed and a positive control sample (non-sterilized BI) was also tested for each cycle.

5) The BI carriers in TSB were incubated at 55-60°C for 7 days and the results were recorded. The SporView BI's were incubated for 24 hours at 55-60°C per the manufacturer's instructions. Steps #1 - #5 were repeated for the sterilization case until three consecutive cycles had been completed.

Biological Indicator Information:

A population verification was performed on the BIs utilized in testing. BI carriers were homogenized and enumerated by standard plate count. As outlined in AAMI TIR12:2010, Section 6.5.2.1, the biological challenge for each indicator/inoculation site should be greater than or equal to $6F_{bio}$.

Examples: Log_{10}(BI population) x $D_{121.1}$ value = F_{bio}
$Log_{10}(1.0 \times 10^4) \times 1.5$ minutes = 6
$Log_{10}(1.0 \times 10^6) \times 1.0$ minutes = 6

BI Type	Lot #	Population	D-value at 121°C (min.)	Expiration Date
Crosstex Strip (BS-106)	RU88	2.0×10^6	2.0	07/2020
Crosstex Thread (THS-06)	1625001	1.8×10^6	1.6	03/2020
SPORVIEW Self-contained (SCS-100)	6851	2.1×10^5	1.9	10/2021

RESULTS:

See attached.

CONCLUSION:

In the three pre-vacuum autoclave cycles, 1.5 minutes at 132°C was sufficient to sterilize the BI's in the Buxton Orthopedic Surgical Instruments Tray when seeded with (7) BI carriers impregnated with *Geobacillus stearothermophilus* and (2) SporView self-contained BI's. Since this is a half cycle validation at a lesser temperature, the 3 minute full cycle exposure time at 134 °C will provide the required Sterility Assurance Level (SAL) of 10^{-6}. **This validation met the acceptance criteria. The validated time of 3 minutes exposure is the minimum time recommended for the pre-vacuum autoclave cycles in AAMI ST79 for wrapped instruments.**

Note: This data is for reference purposes only and demonstrates the ability of the device to be sterilized under similar conditions. The actual sterilization times may differ with increased bioburden and/or greater amounts of organic material on the device. Following proper cleaning procedures, applicable hospital and AAMI guidelines, and the autoclave instruction manual are essential to successful sterilization.

REFERENCES:

1. AAMI TIR12:2010, *Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A Guide for Medical Device Manufacturers*
2. ANSI/AAMI ST79:2017, *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities*
3. ANSI/AAMI/ISO 17665-1:2006/(R) 2013, *Sterilization of Health Care Products – Moist Heat – Part 1: Requirements for the Development, Validation, and Routine Control of a Sterilization Process for Medical Devices*
4. Food and Drug Administration Guidance for Industry (March 17, 2015), *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling*

Analyst: _____ Date: 2/24/20

Reviewed By: _____ Date: 2/24/20

RESULTS:

BUXTON ORTHOPEDIC SURGICAL INSTRUMENTS TRAY

PRE-VACUUM CYCLE #1 (134°C – 1.5 Minutes) **Date: 02/05/20**

(9) TEST BI'S: (7) BI Carriers and (2) SporView BI'S

# BI'S POSITIVE	# BI'S NEGATIVE
0	9

Minimum Instrument Case Accumulated F_0: 26.41
Chamber Accumulated F_0: 34.50

Negative (Media) Control: Negative
Positive Controls: Positive

PRE-VACUUM CYCLE #2 (134°C – 1.5 Minutes) **Date: 02/05/20**

(9) TEST BI'S: (7) BI Carriers and (2) SporView BI'S

# BI'S POSITIVE	# BI'S NEGATIVE
0	9

Minimum Instrument Case Accumulated F_0: 28.84
Chamber Accumulated F_0: 34.25

Negative (Media) Control: Negative
Positive Controls: Positive

PRE-VACUUM CYCLE #3 (134°C – 1.5 Minutes) **Date: 02/05/20**

(9) TEST BI'S: (7) BI Carriers and (2) SporView BI'S

# BI'S POSITIVE	# BI'S NEGATIVE
0	9

Minimum Instrument Case Accumulated F_0: 24.41
Chamber Accumulated F_0: 29.00

Negative (Media) Control: Negative
Positive Controls: Positive

TEST START DATE: 02/05/20 **TEST COMPLETION DATE:** 02/12/20

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134°C PRE-VACUUM STEAM STERILIZATION VALIDATION
SURGICAL INSTRUMENTS SET
PROTOCOL REV. 01/23/20

Sponsor

Buxton BioMedical, Inc.
11 Melanie Lane, Unit 8
East Hanover, NJ 07936

Test Facility

Mycoscience Labs
25 Village Hill Rd.
Willington, CT 06279

Purpose of the Study

To validate the steam sterilization pre-vacuum cycle of 3 minutes at 134°C in order to establish a Sterility Assurance Level (SAL) of 10^{-6} for the listed test articles.

Test System and Justification

This study will evaluate the sterilization efficacy of the devices in conformance with the AAMI TIR12: *Designing, Testing, and Labeling Reusable Medical Devices For Reprocessing in Health Care Facilities: A Guide For Medical Device Manufacturers* and ANSI/AAMI/ISO 17665-1:2006/(R) 2013, *Sterilization of Health Care Products – Moist Heat – Part 1: Requirements for the Development, Validation, and Routine Control of a Sterilization Process for Medical Devices*. The specific methodology is the overkill procedure described in Section 6.5 of this guidance document. Half cycles will be used rather than full cycles to establish a SAL of 10^{-6}.

The validated cycle will also meet the cycle time recommended in ANSI/AAMI ST79:2017. The cycle validated is for wrapped devices using the pre-vacuum cycle at 134°C with a 3 minute exposure time. **The 3 minute cycle time will be validated by 1.5 minute half cycles without any additional drying time using a lesser autoclave temperature of 132°C, thus providing worst case validation conditions.** The sterilizer used for this study is the Consolidated SSR-3A that has 510k clearance for use in healthcare facilities.

Test Articles

(1) Buxton Orthopedic Surgical Instruments Tray, Including:

1. Carbon Fiber Blade, 30x30mm, Catalog # 52-5855-CF
2. Frazier Tube, 45°, 130x2.0mm, 6Fr, Catalog # 71-1320
3. Frazier Suction, 3F, 60°, 135mm, Catalog # 70-060-1303
4. Chisel Handle, Catalog # 24-4201
5. Arthroscopic Cup Curette, 13cm, 5°, Size 2, Catalog # 46-6205
6. Revolver Roulette Sterilizing Case & Lid, small, Catalog # 853-90-1010
7. Revolver Roulette Handle, Satin, Catalog # 853-0001
8. Revolver Roulette Handle, Ceramic finish / silicone, Catalog # 853-0004
9. Roulette Shaft, 200mm x 4mm bite, 40°, Catalog # 853-3246
10. Roulette Shaft, 200mm x 3mm bite, 40°, Catalog # 853-5236
11. Roulette Shaft, Ceramic, 300mm x 2mm bite, 40°, Catalog # 853-3928

Control Articles

A non-sterile Biological Indicator (BI) of each type used will serve as a positive control for each cycle.

Test Equipment/Materials

Bioshield Wrap (#K983719)
Consolidated SSR-3A Sterilizer (#K041833)
GE Kaye Validator

Methods

1.0 134°C Pre-Vacuum Half Cycle Validation with 1.5 Minute Exposure Time.

1.1 Inoculum Level and Positioning

1.1.1 Use BI's where the design permits with a nominal concentration of $\geq 1.0 \times 10^6$ *Geobacillus stearothermophilus* or an $F_{bio} = 6$. Seed the BI's in the regions most difficult to sterilize, for example, lumens, mated surfaces, and adjacent thermally dense instruments. Use a minimum of (7) BI carriers (strips and/or threads) in the case. Additionally, (2) SporView self-contained BI's that are FDA cleared for use in healthcare facilities, will be distributed in the case. See attached photos for the locations of the BI's in the case.

1.2 Sterilize the case after wrapping it in a double layer of 510k cleared sterilization wrap using the envelope technique per AAMI ST79 recommendation. **Sterilize the case using a 1.5 minute half cycle exposure time at a lesser temperature 132°C without any drying time.** Use the GE-Kaye Validator to monitor all the cycles and provide accumulated lethality (AF_o) data. A minimum of two thermocouples will be used in the case, and one chamber thermocouple will be used for monitoring the cycles. See attached photo for thermocouple location(s).

1.3 Aseptically transfer the sterilized test case containing the BI carriers and SporView BI's to a laminar flow hood. Perform sterility testing on the BI carriers and incubate at 55-60°C for 7 days.

1.4 Incubate the SporView BI's per the manufacturer's instructions for 24 hours at 55-60°C.

1.5 Repeat steps 1.1 - 1.4 until three consecutive 132°C pre-vacuum sterilization cycles have been completed.

2.0 Acceptance Criteria

2.1 The validation of the recommended pre-vacuum exposure time of 3 minutes at 134°C will be successful if the half cycle time of 1.5 minutes at the lesser temperature of 132°C sterilizes all the seeded BI's, which in turn validates the 10^{-6} SAL.

References:

1. AAMI TIR12: 2010, *Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A Guide for Medical Device Manufacturers*
2. ANSI/AAMI ST79:2017: *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities*
3. ANSI/AAMI/ISO 17665-1:2006/(R) 2013, *Sterilization of Health Care Products – Moist Heat – Part 1: Requirements for the Development, Validation, and Routine Control of a Sterilization Process for Medical Devices*
4. Food and Drug Administration Guidance for Industry (March 17, 2015). *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling*

Approvals:

Amy Cameron — Mycoscience Representative — Date: 1/28/20

AWS — Buxton BioMedical Representative — Date: 29 JAN 2020

Buxton Orthopedic Surgical Instruments Tray