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TEST REPORT
270°F PRE-VACUUM STEAM STERILIZATION VALIDATION
BUXTON BIOMEDICAL ORTHOPEDIC SURGICAL INSTRUMENTS

CLIENT: Buxton BioMedical, Inc.
15A Melanie Lane 7
East Hanover, NJ 07936

TEST#: 13-1524 BBM

DATE: 09/12/13

REPORT TO: Alice Schussler

TEST SYSTEM AND JUSTIFICATION:

This study evaluated the sterilization efficacy of the devices in conformance with the AAMI TIR No. 12:2010: *Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A Guide for Device Manufacturers* and ANSI/AAMI/ISO 17665-1:2006, *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.

The validated cycle meets the cycle times recommended in ANSI/AAMI ST79(A1:2010, A2:2011, A3:2012). The cycle validated is for wrapped devices using the pre-vacuum cycle @ 270°F with a 4 minute exposure time. The 4 minute time cycle time was validated by 2 minute half cycles without any additional drying time, 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:

Buxton Orthopedic Surgical Instruments:

1) Cat. #24-6362, Mod.Mini-Open Frame f/3rd arm
2) Cat. #24-5914, Subscapularis Spreader
3) Cat. #52-5724, Alm Retriever,70mm, blunt, 8mm
4) Cat. #54-3103, Tndn Braid Forceps,str,adult size
5) Cat. #88-7823, Bandit-Stille Rongeur, 330x3mm
6) Cat. #335-112-20, PigSticker Punch N Pull Retrev
7) Cat. #843-5242, Punch, 200x4mm,40°up,Ejec,TFP
8) Cat. #845-5104, Punch, 200x4mm,Lite Up-cvd
9) Cat. #SE-3035, Revolver Endo Shaft, 300 x 3.5, 40° (Assembled)
10) Cat. #56-5141, Half Round Rasp, straigh
11) Cat. #46-1210, Arthro Curette, 13cm, 10°, #2
12) Cat. #51-7730, Irrigating Cannula, ang, 30 ga
13) Cat. #852-R3-3936, Rev2 Shaft Op3, 195 x 3.2, 40° (Assembled)
14) Cat. #54-3011, K-K Tendon Retrvr,flex,2.0mm
15) Cat. #52-5152, Hook, blnt, 1-prong, flex neck
16) Cat. #52-9000, Finger/Toe Tourniquet

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TEST PROCEDURE:

Reference Mycoscience Protocol: "270°F Pre-Vacuum Steam Sterilization Validation Buxton Biomedical Orthopedic Surgical Instruments, Protocol Rev. 08/28/13"

1) A total of (12) Biological Indicators (BI's) were used in the instrument tray for each cycle of the three sterilization validation cycles. The BI's were placed throughout the tray in instruments or directly adjacent instruments that would be considered "worst case" or more difficult to sterilize. The tray was seeded with (10) BI carriers impregnated with a minimum concentration of 1.0 X 10^6 CFU of *Geobacillus stearothermophilus* (NAMSA Sportrol #SUS-06) and (2) SPS Medical Sporview Self-Contained BI's. See attached photos for BI locations.

2) Two thermocouples were placed in the sterilization tray 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 tray was wrapped in a two layers of sterilization wrap as recommended in ANSI/AAMI ST79. Bioshield sterilization wrap (#K983719) was used and the tray was autoclaved @ 270°F for 2 minutes in the Consolidated SSR-3A Digital Sterilizer. The sterilizer was set to the 3 pulse pre-vacuum mode without any drying time. After sterilization, the tray was transferred to a laminar flow hood for sterility testing.

4) The BI carriers were aseptically removed from the tray 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 @ 55-60°C for 7 days and the results were recorded. The SporView BI's were incubated for 24 hours @ 55-60°C per the manufacturer's instructions. Steps #1 - #5 were repeated for the sterilization tray and instruments until three consecutive cycles had been completed.

Biological Indicator Information:

A population verification was performed on the BIs utilized in testing. BI strip and suture 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 6*F*bio.

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

BI Type	Lot #	Population	D-value @ 121°C (min.)	Expiration Date
NAMSA BI Strip	S77118	2.79×10^6 CFU	1.9	04/2014
SPORVIEW Self-contained	6321	3.62×10^5 CFU	1.5	06/2014

RESULTS:

See attached.

CONCLUSION:

In the three pre-vacuum autoclave cycles, 2 minutes @ 270°F was sufficient to sterilize the BI's in and adjacent the "worst case" Buxton Orthopedic Surgical Instruments when seeded with (10) BI carriers containing 10^6 *Geobacillus stearothermophilus* and (2) SporView Self-Contained BI's. Since this is a half cycle validation, the 4 minute full cycle exposure time will provide the required sterility assurance level (SAL) of 10^{-6}. **This validated time of 4 minutes exposure is the minimum time recommended for the 270°F 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.

VALIDATION TEST REFERENCES:

1. AAMI TIR No. 12: 2010, *Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A Guide for Medical Device Manufacturers*
2. ANSI/AAMI ST79:2010 (A1:2010, A2:2011, A3:2012): *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities*
3. ANSI/AAMI/ISO 17665-1:2006, *Sterilization of Health Care Products – Moist Heat – Part 1: Requirements for the Development, Validation, and Routine Control of a Sterilization Process for Medical Devices*

Analyst: Amy Cameron Date: 9/12/13

Reviewed By: R. Fournault Date: 9/12/13

RESULTS:

BUXTON ORTHOPEDIC SURGICAL INSTRUMENTS

PRE-VACUUM CYCLE #1 (270°F – 2 Minutes) **Date: 09/03/13**

(12) TEST BI'S (10) BI Carriers and (2) SporView BI'S

# BI'S POSITIVE	# BI'S NEGATIVE
0	12

Minimum Instrument Case Accumulated F_0: 14.35
Chamber Accumulated F_0: 26.31
Negative (Media) Control: Negative
Positive Controls: Positive

PRE-VACUUM CYCLE #2 (270°F – 2 Minutes) **Date: 09/03/13**

(12) TEST BI'S**:** (10) BI Carriers and (2) SporView BI'S

# BI'S POSITIVE	# BI'S NEGATIVE
0	12

Minimum Instrument Case Accumulated F_0: 18.56
Chamber Accumulated F_0: 25.58
Negative (Media) Control: Negative
Positive Controls: Positive

PRE-VACUUM CYCLE #3 (270°F – 2 Minutes) **Date: 09/04/13**

(12) TEST BI'S**:** (10) BI Carriers and (2) SporView BI'S

# BI'S POSITIVE	# BI'S NEGATIVE
0	12

Minimum Instrument Case Accumulated F_0: 16.61
Chamber Accumulated F_0: 29.94
Negative (Media) Control: Negative
Positive Controls: Positive

TEST START DATE: 09/03/13 **TEST COMPLETION DATE:** 09/11/13

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270°F PRE-VACUUM STEAM STERILIZATION VALIDATION
BUXTON BIOMEDICAL ORTHOPEDIC SURGICAL INSTRUMENTS
PROTOCOL REV. 08/28/13

Sponsor

Buxton BioMedical, Inc.
15A Melanie Lane 7
East Hanover, NJ 07936

Test Facility

Mycoscience Labs
25 Village Hill Rd.
Willington, CT 06279

Purpose of the Study

To validate the appropriate time required for 270°F steam sterilization pre-vacuum cycles in order to establish a 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 TIR No. 12: *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, *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 ST79:2010(A1:2010, A2:2011, A3:2012). The cycle validated is for wrapped devices using the pre-vacuum cycle @ 270°F with a 4 minute exposure time. The 4 minute cycle time will be validated by 2 minute half cycles without any additional drying time, thus providing worst case conditions. The sterilizer used for this study is the Consolidated SSR-3A that has 510k clearance for use in healthcare facilities. The wrap used for this study is Bioshield Wrap that has 510k clearance for use in healthcare facilities (#K983719).

Test Articles

Buxton Orthopedic Surgical Instruments:

1) Cat. #24-6362, Mod.Mini-Open Frame f/3rd arm
2) Cat. #24-5914, Subscapularis Spreader
3) Cat. #52-5724, Alm Retriever,70mm, blunt, 8mm
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9) Cat. #SE-3035, Revolver Endo Shaft, 300 x 3.5, 40° (Assembled)
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15) Cat. #52-5152, Hook, blnt, 1-prong, flex neck
16) Cat. #52-9000, Finger/Toe Tourniquet

Refer to Buxton Validation Protocol, Report #VP-020513 "Validation of Steam Sterilization Cycles for Buxton Orthopedic Surgical Instruments"

Control Articles

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

Test Instruments

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

Methods

1.0 270°F Pre-Vacuum Half Cycle Validation with 2 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*. Seed the BI's in the regions most difficult to sterilize. Use a minimum of (10) BI carriers (strips and/or sutures) in the tray. Additionally, (2) SporView self-contained BI's that are FDA cleared for use in healthcare facilities, will be distributed in the tray. See attached photo for the locations of the BI's in the tray.

1.2 The instruments will be sterilized after being placed in a perforated sterilization tray and wrapped in a double layer of 510k cleared sterilization wrap using the envelope technique per AAMI ST79 recommendation. Use a 2 minute half cycle exposure time at 270°F without any drying time. Do not sterilize the positive control samples. Use the GE-Kaye Validator to monitor all the cycles and provide accumulated lethality (AF_o) data. A minimum of one product thermocouple in the tray and one chamber thermocouple will be used for monitoring the cycles. See attached photo for thermocouple location.

1.3 Aseptically transfer the sterilized articles with the BI strips and SporView BI's to a laminar flow hood. Perform sterility testing on the BI carriers and incubate @ 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 270° F pre-vacuum sterilization cycles have been successfully completed.

2.0 Acceptance Criteria

2.1 The recommended exposure time of 4 minutes will be successful if the half cycle time of 2 minutes kills all the seeded BI's and if the cycle provides a minimum AF_o of 12.0 or greater.

References:

1. AAMI TIR No. 12: 2010, *Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A Guide for Medical Device Manufacturers*
2. ANSI/AAMI ST79:2010 (A1:2010, A2:2011, A3:2012): *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities*
3. ANSI/AAMI/ISO 17665-1:2006, *Sterilization of Health Care Products – Moist Heat – Part 1: Requirements for the Development, Validation, and Routine Control of a Sterilization Process for Medical Devices*

Approvals:

Richard Arsenault — Mycoscience Representative — 8/30/13 — Date

Alice Schuss — Buxton BioMedical Representative — 8/30/13 — Date

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