MycoScience
Specialists in Microbiology & Regulatory Affairs

TEST REPORT
134°C PRE-VACUUM DRYING TIME VALIDATION
SURGICAL INSTRUMENTS SET

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

TEST#: 20-0182 BUX

DATE: 02/17/20

REPORT TO: Alice Schussler

PURPOSE OF THE STUDY:

To validate the appropriate drying time required for the 3 minute 134°C steam sterilization pre-vacuum cycle to ensure the listed test articles are dry and ready for use after cycle completion.

TEST SYSTEM AND JUSTIFICATION:

This study evaluated the drying efficacy of the devices in conformance with the Food and Drug Administration Guidance for Industry (March 17, 2015), *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling* , 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 validated full cycle and the associated minimum drying time meet the cycle time recommended in ANSI/AAMI ST79:2017. **The pre-vacuum cycle is a 3 minute 134 °C cycle with a minimum 16 minute dry time that will be validated using a lesser autoclave temperature of 132 °C, thus providing worst case validation conditions.** The sterilizer used for this study was 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.

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:

The wrapped case was weighed prior to each cycle.

TEST INSTRUMENTS:

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

TEST PROCEDURE:

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

1.0 134°C Pre-Vacuum Cycle with 3 Minute Exposure Time and 16 Minute Drying Time

1.1 The case was wrapped with two layers of Bioshield wrap using the envelope technique per AAMI ST79 recommendations. The wrapped case was weighed prior to sterilization, and the weight was recorded. **The case was then sterilized for a 3 minute cycle exposure time at a lesser temperature of 132°C with 16 minutes of drying time.**

1.2 After sterilization, the wrapped case was removed and weighed. The weight was recorded and the weight differential was noted before vs. after sterilization and drying. The case and the contents were inspected for visible moisture. The wrap was also inspected for any visible moisture.

1.3 Steps 1.1 - 1.2 were repeated until three consecutive 132° C sterilization cycles had been completed.

2.0 Success Criteria – Validation of Recommended Drying Time

2.1 The recommended drying time is successful if the weight differential of the case after sterilization does not exceed 0.1% of the pre-sterilization weight, and there is no evidence of moisture on or within the sterilized package, wrap and/or instruments.

RESULTS:

PRE-VACUUM CYCLE – 3 MINUTES AT 134°C, WITH 16 MINUTES DRY TIME

BUXTON ORTHOPEDIC SURIGICAL INSTRUMENTS TRAY				
Cycle	**Date**	**Weight in Grams Before Sterilization**	**Weight in Grams Post Sterilization**	**Visible Moisture**
1	02/07/20	2,330g	2,330g	No
2	02/10/20	2,330g	2,330g	No
3	02/10/20	2,330g	2,330g	No

CONCLUSION:

The case meets the success criteria for the 134°C Pre-Vacuum cycle with a 3 minute cycle time and a 16 minute dry time. There was no evidence of moisture on or within the sterilized package, wrap, instruments and/or implants. The Buxton Orthopedic Surgical Instruments Tray had no recorded weight gain after the pre-vacuum sterilization cycles.

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: 2/18/2020

Reviewed By: R. Arsenault Date: 2/21/20

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134°C PRE-VACUUM DRYING TIME 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 appropriate drying time required for the 3 minute 134°C steam sterilization pre-vacuum cycle to ensure the listed test articles are dry and ready for use after cycle completion.

Test System and Justification

This study will evaluate the drying efficacy of the devices in conformance with the Food and Drug Administration Guidance for Industry (March 17, 2015), *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling* , 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 validated full cycle and the associated minimum drying times will meet the cycle time recommended in ANSI/AAMI ST79:2017. **The 3 minute 134°C pre-vacuum cycle and 16 minute dry time, will be validated by 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. The wrap used for this study is a Bioshield Wrap that has 510k clearance for use in healthcare facilities (#K983719).

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
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11. Roulette Shaft, Ceramic, 300mm x 2mm bite, 40°, Catalog # 853-3928

Control Articles

The test articles will be weighed prior to each cycle.

Test Equipment/Materials

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

Procedure:

1.0 134°C Pre-vacuum Cycle with 3 Minute Exposure Time and 16 Minute Drying Time

1.1 Wrap the case in a double layer of 510k cleared sterilization wrap using the envelope technique per AAMI ST79 recommendation. Weigh the case prior to sterilization and record the weight. **The 3 minute 134°C pre-vacuum cycle will be validated using a 3 minute exposure time at a lesser temperature of 132°C, with 16 minutes of drying time.**

1.2 After sterilization, remove and weigh the wrapped case. Record the weight and note the weight differential before vs. after sterilization and drying. Remove the wrap and examine for any residual moisture.

1.3 Repeat steps 1.1 - 1.2 until three consecutive 132° C sterilization cycles have been completed.

2.0 Success Criteria – Validation of Recommended Drying Time

2.1 The recommended drying time is successful if the weight differential of the wrapped case after sterilization does not exceed 0.1% of the pre-sterilization weight, and there is no evidence of moisture on or within the sterilized package, wrap, and/or instruments.

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*
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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

1/28/2020
Date

Buxton BioMedical Representative

29 JAN 2020
Date

Buxton Orthopedic Surgical Instruments Tray