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FINAL REPORT

Confidential & Proprietary

Study No. 0707-137

Velmed, Inc.
the Stopper™
Steam Gravity Validation

Prepared for:

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9/5/07
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Study No.:	0707-137
Sponsor:	Velmed, Inc. 135 Cumberland Rd., Suite 109 Pittsburgh, PA 15237
Study Director:	Gary Socola Vice President, Scientific Affairs SPSmedical Supply Corp. 6789 West Henrietta Road Rush, NY 14543
Study Personnel:	Veronica Falkevitz: Laboratory Technician
Test Objective:	To validate the sterilization efficacy of the Stopper™ when processed in a steam gravity sterilizer at 250°F (121°C) for thirty (30) minutes exposure time.
Test Samples:	the Stopper™, See Bill of Materials, Table 1

References:

1. Pflug, IJ, and Holcomb, RG, "Principles of the Thermal Destruction of Microorganisms" in Disinfection, Sterilization and Preservation, (SS Block, ed). Lea & Febiger, Philadelphia, 4th edition, 1991.
2. United States Pharmacopeia. Current Edition.
3. AAMI TIR12:2004. Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities. A Guide for Device Manufacturers.
4. SPSmedical Internal Standard Operating Procedures.
5. AAMI/ISO 14937:2000 Sterilization of Health Care Products – General Requirements for Characterization of a Sterilizing Agent and the Development, Validation and Routine Control of a Sterilization Process.
6. ANSI/AAMI ST79:2006 Comprehensive guide to steam sterilization and sterility assurance in health care facilities.
7. ANSI/AAMI ST 8:2001 Hospital Steam Sterilizers.

1.0 INTRODUCTION:

This final report details the methods used in validating the sterilization efficacy of the Stopper™ when processed at 250°F for thirty (30) minutes exposure time in a steam gravity sterilization cycle. A method of steam sterilization was validated to a sterility assurance level (SAL) of 10^{-6} using the biological indicator (BI) overkill method. The SAL was achieved by placing at least 1.0×10^6 spores of *Geobacillus stearothermophilus* in between the Stopper™ and tray and processing at one-half the expected full cycle exposure time. A total of eight (8) Stoppers were used with a fully loaded tray wrapped in Kimguard® and processed in a steam gravity sterilization cycle of 250°F for a half-cycle of fifteen (15) minutes. The BI's were aseptically transferred to culture media and incubated as recommended by the indicator manufacturer. All testing was performed in triplicate.

2.0 JUSTIFICATION:

The overkill method was selected to verify the sterilization efficacy of the Stopper™ per AAMI guidelines. In this method, validation was accomplished by demonstrating that a minimum of 1.0×10^6 of highly resistant *Geobacillus stearothermophilus* spores were killed in a half-cycle. A full cycle would therefore result in a 12-log reduction of spores and produce a 10^{-6} sterility assurance level (SAL), which reflects a one-in-a-million chance of a nonsterile item. This study provides the sponsor with sterilization data for the product. It is the sponsor's responsibility to apply this data, along with functionality and manufacturing data, to the products label claims.

3.0 EQUIPMENT AND MATERIALS:

3.1 Sample: the Stopper™ (Bill of Materials, Table 1)
3.2 Test Organism: *Geobacillus stearothermophilus*
  3.2.1 BI strips # RT85
3.3 Integrators: SPSmedical Supply, STEAM*Plus*™ Sterilization Integrator lot # 207
3.4 Sterilizer: AAMI ST8:2001 Compliant Hospital Steam Sterilizer, SPSmedical Equipment # 059
3.5 HEPA Laminar Flow Hood: SPSmedical Equipment # 045
3.6 Culture Media:
  3.6.1 Soybean Casein Digest Broth (SCDB) lot # 07108, 07155
3.7 Incubator: 55-60°C SPSmedical Equipment # 039
3.8 Kimguard® One-Step® KC400
3.9 SPSmedical Steam Indicator Tape

4.0 STEAM HALF-CYCLE DESCRIPTION:

Steam gravity cycles with the following half-cycle parameters were utilized during testing:

Temperature.....250°F (121°C)
Sterilization Time.....15 minutes
Dry Time.....30 minutes

5.0 PROCEDURE:

5.1 A warm up cycle was run in the sterilizer to ensure functionality.
5.2 Eight (8) Stopper™ corners were obtained.
5.3 One (1) BI was placed in between each tray and each Stopper™ corner for a total of eight (8) BI's.
5.4 Two (2) STEAM*Plus*™ Integrators were placed in each tray.
5.5 The tray was fully loaded and wrapped with Kimguard® One-Step® KC400 to achieve a maximum total weight of 25 lbs.
5.6 The wrapped tray was placed in a fully loaded chamber.

5.7 The tray was processed at the half cycle parameters of 250˚F (121˚C) for fifteen (15) minutes with thirty (30) minutes dry time.

5.8 The tray was removed after cycle completion and placed in Laminar Flow Hood.

5.9 The BI's were aseptically removed and transferred to tubes of SCDB media pre-labeled for traceability purposes.

5.10 Steps 5.2 thru 5.9 were repeated two (2) additional times for a total of three (3) half cycles.

5.11 An un-inoculated tube of SCDB was incubated as a negative control.

5.12 One (1) unprocessed BI strip of the same lot was transferred into a separate tube of SCDB and incubated as a positive control.

5.13 One (1) tube of SCDB was uncapped during transfers as an environmental control.

5.14 All samples and controls were incubated at 55-60˚C for seven (7) days and monitored daily for growth.

5.15 Results were recorded (see Table 2).

6.0 RESULTS:

All BI test samples were negative for growth. The negative and environmental controls were negative for growth. The positive controls were positive for growth. All integrators reached the safe zone.

7.0 CONCLUSION:

Based on results of testing, the Stopper™ was found to be safe and effective at achieving an SAL 10^{-6} when processed in the following pre-vacuum steam sterilization cycle:

Temperature.....250°F (121°C)
Exposure Time.....30 minutes
Dry Time.....30 minutes

Bill of Materials

QTY	Item	P/N
8	the Stopper™	5100

Table 1

Sample Test Locations

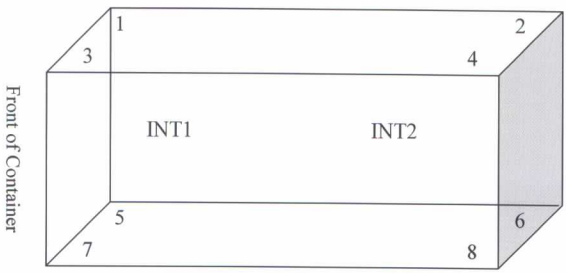

Diagram 1

INT = Integrator placement
1-8 = BI placement

Biological Indicator Test Results

Sample Identification		Cycle #1	Cycle #2	Cycle #3
BI Strip	1	N	N	N
	2	N	N	N
	3	N	N	N
	4	N	N	N
	5	N	N	N
	6	N	N	N
	7	N	N	N
	8	N	N	N
Environmental Control - SCDB		N	N	N
Positive Control – BI Strip		P	P	P
Negative Control – SCDB		N	N	N

Table 2

N = Negative, no growth
P = Positive for growth