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FINAL REPORT

Confidential & Proprietary

Study No. 1007-190

Velmed, Inc.
Stopper®
STERRAD® 100S Validation

Prepared for:

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8/31/10
Date

Study No.:	1007-190
Sponsor:	Velmed, Inc. 23D Dewey Lane Gibsonia, PA 15044
Study Director:	Don Tumminelli Manager, Validation & Testing Services 6789 West Henrietta Road Rush, NY 14543
Study Personnel:	Alex Belik – SPSmedical Laboratory Technician
Test Objective:	To validate the Velmed, Inc. Stopper® for the STERRAD® 100S
Test Samples:	Velmed, Inc. 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. ANSI/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/A2:2009 Steam Sterilization and Sterility Assurance in Health Care Facilities

1.0 INTRODUCTION:

This report details the methods used in evaluating the Velmed, Inc. Stopper® in a STERRAD® 100S sterilization cycle typical of that used in a hospital setting. A method of STERRAD® sterilization was utilized in order to achieve a sterility assurance level (SAL) of 10^{-6} using the biological indicator Overkill method. A total of eight (8) Stoppers were used with a fully loaded wrapped tray. The Stopper and tray corners were seeded with biological indicators containing a minimum of 1.0 x 10^6 *Geobacillus stearothermophilus* spores ATCC 7953 which have been determined to be the most resistant organism to the STERRAD® process. The system was then exposed to one half the expected full cycle. This process was repeated three (3) times in order to statistically validate that the Stopper® can achieve the proper sterility assurance level (SAL) when exposed to a full cycle and does not inhibit sterilant penetration.

2.0 JUSTIFICATION:

The overkill method was selected to verify the sterilization efficacy of the Velmed, Inc. Stopper® per AAMI guidelines. In this method, validation is accomplished by demonstrating that a minimum of 1.0 x 10^6 highly resistant *Geobacillus stearothermophilus* spores will be 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 non-sterile 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 Velmed, Inc. Stopper®: Table 1
3.2 Micromedics Instrument Tray: IN-8820-CF: 19 5/8" x 9 5/8" x 6 5/8"
3.3 Sterilizer: STERRAD® 100S Sterilizer: SPSmedical Equipment # 062
3.4 STERRAD® Chemical Indicator Strip PC 14100: Lot # 336911-03
3.5 STERRAD® SealSure Chemical Indicator Tape PC 14202
3.6 HEPA Laminar Flow Hood: SPSmedical Equipment # 209
3.7 Test Organism: *Geobacillus stearothermophilus* ATCC 7953
  3.7.1 BI Spore Disc: Lot # 097107
  3.7.2 BI Spore Disc: Lot # 136107
  3.7.3 Low Colony Spore Strips: Lot # LG06
3.8 Microbiological Culture Media
  3.8.1 Tryptic Soy Broth (TSB): Lot # 0083242
3.9 59% nominal concentration H_2O_2 Sterilant: Lot # 09J028
3.10 Sterilization Wrap: KIMGUARD OneStep KC 400
3.11 Calibrated incubator at 55-60°C monitored and logged daily: SPSmedical Equipment # 072
3.12 MicroSyringe
3.13 Sterile Lab Transfer Equipment
3.14 Sterile Lab Transfer Attire

4.0 STERRAD® HALF CYCLE DESCRIPTION:

The type of sterilization used for this testing was a typical hospital STERRAD® 100S half cycle with the following parameters:

Pre-Plasma:	10 minutes
Injection:	6 minutes
Diffusion:	2 minutes
Post Plasma:	2 minutes
Injection Volume:	1440µL of 59% H_2O_2

5.0 VALIDATION OF SPORES:

The biological indicators used in testing were verified for population to contain the labeled population of spores within USP limits.

6.0 VALIDATION OF CULTURE MEDIUM:

All media was validated as required by the USP for sterility and growth promotion.

7.0 PROCEDURE:

7.1 Eight (8) Stopper corners were obtained.
7.2 One (1) BI was placed in between each tray and Stopper corner for a total of eight (8) BI's per Figure 1.
7.3 Two (2) STERRAD® Chemical Indicator Strips and a STERRAD® CycleSure BI were placed in the tray per Figure 1.
7.4 The tray was fully loaded and wrapped with one (1) sheet of the Kimguard® One Step® KC400 per AAMI ST79:2006/A2:2009 using the simultaneous envelope fold and secured with STERRAD® SealSure Chemical Indicator Tape.
7.5 The wrapped tray was placed inside the STERRAD® 100S Sterilizer and processed at the half-cycle parameters.
7.6 Following processing, the test samples were removed and placed under a Laminar Flow Hood.
7.7 The BI's were aseptically removed and transferred to tubes of microbiological culture media within the Laminar Flow Hood.
7.8 Steps 7.1 thru 7.7 were repeated two (2) times for a total of three (3) half-cycles.
7.9 During the transfer stage, an environmental control consisting of an uncapped tube of microbiological culture media was exposed.
7.10 At the end of each test day, a positive control (unprocessed BI) was prepared using the test organism.
7.11 At the end of each test day, a negative control consisting of one (1) un-inoculated tube of microbiological culture media was used.
7.12 All samples and controls were incubated at 55-60°C, and monitored daily over the fourteen (14) day incubation period.
7.13 All results were recorded: See Table 2.

8.0 NEGATIVE VERIFICATION TEST:

Following the full incubation period, negative test samples were inoculated with $\leq$ 100 spores of *Geobacillus stearothermophilus* and incubated per USP. The presence of growth verified that the media could still support growth of a low number of the challenge organism and that bacteriostatic substances did not inhibit growth.

9.0 RESULTS:

9.1 All BI sample locations showed no growth of the indicator organism after fourteen (14) days incubation.
9.2 The positive controls were positive for growth.
9.3 The negative control and environmental controls were negative for growth.
9.4 All chemical indicators exhibited a color change from red to yellow/gold.

10.0 CONCLUSION:

Results validate the STERRAD® 100S cycle for the Velmed, Inc. Stopper®. Performance testing has shown that the sterilization efficacy of the Velmed, Inc. Stopper® can be achieved in a hospital STERRAD® 100S sterilization full cycle.

Bill of Materials

Quantity	Description	Part Number
8	Stopper®	7100

Table 1

Velmed, Inc. Stopper™
Inoculation Sites

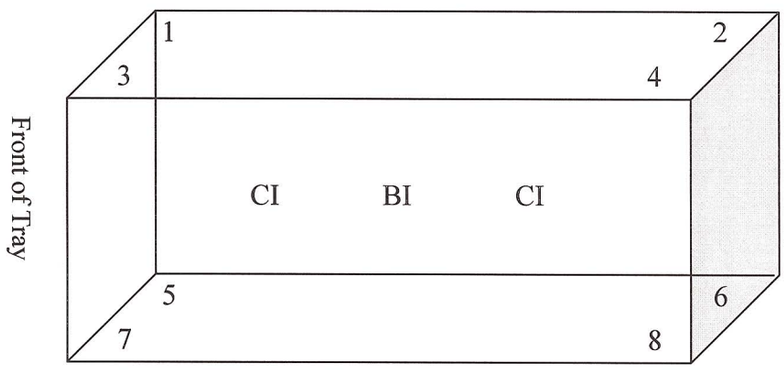

Figure 1

CI = STERRAD® Chemical Indicator Strip
BI = STERRAD® CycleSure BI
1-8 = BI placement between corner of tray and Stopper

Test Results

Sample ID	Cycle # 1	Cycle # 2	Cycle # 3
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
BI	N	N	N
Positive Control – 097107	P	P	P
Positive Control – 136107	N/A	N/A	P
Negative Control – 0083242	N	N	N
Environmental Control – 0083242	N	N	N
Negative Verification	P	P	P

Table 2

N = Negative for growth
P = Positive for growth
N/A = Not Applicable