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FINAL REPORT

STEAM STERILIZATION VALIDATION OF THE AIM "CLEAR FLUSH" LAPAROSCOPIC GRASPER

PROTOCOL NO. 200500602-02

LABORATORY NO. 281138

PREPARED FOR:

AIM INSTRUMENTS

SUBMITTED BY:

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STUDY DIRECTOR GLP CERTIFICATION

[X] USFDA (21 CFR PART 58) [ ] USEPA (40 CFR PART 160)

STEAM STERILIZATION VALIDATION OF
THE AIM "CLEAR FLUSH" LAPAROSCOPIC GRASPER

I CERTIFY THAT THE TEST WAS CONDUCTED IN ACCORDANCE

WITH THE USFDA OR USEPA REGULATIONS AS NOTED ABOVE.

LABORATORY NO. 281138

STUDY DIRECTOR: _____ DATE: 25 Jan 2005

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QAU AUDIT STATEMENT

[X] USFDA (21 CFR PART 58) [ ] USEPA (40 CFR PART 160)

STEAM STERILIZATION VALIDATION OF
THE AIM "CLEAR FLUSH" LAPAROSCOPIC GRASPER

Study Director: Russell W. Lee, B.S.

Final Report Dated: 21 Jan 2005

1. The test was conducted in accordance with the USFDA or USEPA Regulations as noted above. All laboratory results pertaining to this study are recorded in Nelson Laboratories' Data File Number 281138.

2. In accordance with the Good Laboratory Practice Regulations, the Sterility Test phase(s) of this study was inspected by the Quality Assurance Unit on: 12 Jan 2005. The findings of the inspection(s) were reported to Management and to the Study Director on: 19 Jan 2005 and 20 Jan 2005.

3. The Quality Assurance Unit has reviewed this report and has determined that the methods and standard operating procedures are accurately described, and that the reported results accurately reflect the raw data.

4. The name of the study director, the names of other scientists or professionals, and the names of all supervisory personnel, involved in the study:

Russell Lee	Dr. Jerry Nelson
Emily Mitzel	Jeff Hills
Steven Jensen	Wallace Archer
Jason Pope	

QUALITY ASSURANCE: Brandy Giles DATE: 25 Jan 2005

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STEAM STERILIZATION VALIDATION OF THE "CLEAR FLUSH" LAPAROSCOPIC GRASPER

LABORATORY NUMBER:	281138
PROTOCOL NUMBER:	200500602-02
SAMPLE SOURCE:	AIM Instruments
SAMPLE IDENTIFICATION:	AIM "Clear Flush" Laparoscopic Grasper
NUMBER OF TEST SAMPLES:	3
DEVIATIONS:	None
DATA ARCHIVE LOCATION:	Sequentially by lab number
PROTOCOL APPROVAL DATE:	11 Jan 2005
SAMPLE RECEIVED DATE:	29 Dec 2004
LAB PHASE START DATE:	11 Jan 2005
LAB PHASE COMPLETION DATE:	20 Jan 2005
REPORT ISSUE DATE:	21 Jan 2005
TOTAL NUMBER OF PAGES:	14

INTRODUCTION:

This report details the methods used in validating the recommended steam sterilization procedures. One method of prevacuum steam sterilization and one method of gravity steam sterilization were validated to a sterility assurance level (SAL) of 10^{-6} using the biological indicator (BI) overkill method. *Geobacillus stearothermophilus* ATCC #7953 was the indicator organism.

PROCEDURES:

BI Population Verification for Validation Parameters:

The population for each type of BI was confirmed by serial dilutions after heat-shocking at 95-100°C for 15 minutes. Dilutions were plated onto soybean casein digest agar (SCDA) and incubated at 55-60°C for 48 ± 2 hours. The D-Value is determined by the manufacturer at 121.1 ± 0.5°C.

BI TYPE	MANUFACTURER	LOT #	POPULATION	D-VALUE	EXPIRATION DATE
Suture	Raven Laboratories	3077053A	3.4 x 10^5CFU/suture	N/A	12/05
Strip	SPS Medical	RT60	1.7 x 10^6CFU/strip	2.2 Min	14 Jul 2006
Strip	SPS Medical	RT47	2.5 x 10^6CFU/strip	1.9 Min	July 29, 2005

Growth Promotions For Sterility Media:

G. stearothermophilus was grown, heat shocked, and diluted to <100 CFU/0.5 mL. Three tubes of media from each lot number were inoculated with <100 CFU of the *G. stearothermophilus* suspension and the suspension was plated in triplicate onto SCDA to verify the titer. The plates and tubes were incubated at 55-60°C for 24-120 hours. After incubation, the plates were counted and an inoculating titer was determined. The tubes were scored for the presence of growth.

Steam Sterilization Validations:

An SAL of 10^{-6} using one prevacuum steam sterilization method and one gravity steam sterilization method were validated using the BI overkill method. Three half cycles per parameter were performed on the sample.

Product Inoculation:

SITE #	BI TYPE	DEVICE NAME	INOCULATION LOCATION
1	Suture	Pivot Screw	Between screw and handle
2	Strip	Metal Shaft	Around shaft
3	Suture	Metal Shaft	In lumen at distill end

A visual demonstration of site locations can be found in Figure 1.

Steam Sterilization:

Each device was individually wrapped in two layers of 2-ply, approximately 140 count cotton muslin using sequential wrapping techniques. The pre-processing weights of each device were recorded.

The prepared devices were placed into the "cold" spot (typically over the drain) of the steam sterilizer and sterilized for a total of three half cycles per parameters listed below:

Sterilizer Type:	Prevacuum
Preconditioning Pulses:	3
Minimum Temperature:	132°C
Half Cycle Time:	2 minutes
Minimum Dry Time:	0 minutes
Sample Configuration:	Wrapped device

Sterilizer Type:	Gravity
Minimum Temperature:	132°C
Half Cycle Time:	5 minutes
Minimum Dry Time:	0 minutes
Sample Configuration:	Wrapped device

Following the completion of each half cycle, the device was removed from the sterilizer and the post-processing weights were recorded. The pre- and post-processing weights did not differ by more than 3%. The device was transferred to an ISO class 5 (class 100) HEPA-filtered hood to cool.

Within one hour after sterilization, the BIs were transferred to sterile tubes filled with soybean casein digest broth (SCDB). For an environmental control, a tube of SCDB was left open during the sterility testing of the BIs. For a positive control, a tube of SCDB was inoculated with an unprocessed BI and a tube of SCDB was inoculated with an unprocessed spore suture. For a negative control, an unopened tube of SCDB was incubated along with the BIs. The BIs and controls were incubated at 55-60°C for 7 days and observed for growth of the challenge organism.

RESULTS:

Results for the validated prevacuum parameters can be found in Table 1. Results for the validated gravity parameter can be found in Table 2.

Pre- and post- weights for the validated prevacuum cycles can be found in Table 3. Pre- and post-weights for the validated gravity cycles can be found in Table 4.

CONCLUSION:

Interpretation of the data is the responsibility of the sponsor and no conclusion can be made by Nelson Laboratories, Inc.

VALIDATED STERILIZATION CYCLES:

Results validate the sample for the following sterilization cycles:

Sterilizer Type:	Prevacuum
Preconditioning Pulses:	3
Minimum Temperature:	132°C
Full Cycle Time:	4 minutes
Minimum Dry Time:	0 minutes
Sample Configuration:	Wrapped device

Sterilizer Type:	Gravity
Minimum Temperature:	132°C
Full Cycle Time:	10 minutes
Minimum Dry Time:	0 minutes
Sample Configuration:	Wrapped device

STATEMENT OF UNCERTAINTY:

The uncertainty of the sterility test is the ability to detect the growth of organisms if present. This is demonstrated by inoculating each lot of media with <100 organisms and showing growth. No standard uncertainty has been assigned to this test.

Technical Reviewer

Russell W. Lee, B.S.
Study Director

25 Jan 2005
Study Completion Date

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TABLE 1. BI Test Results for the 2 minute, Prevacuum 132°C Half Cycles

IDENTIFICATION	RUN #1	RUN #2	RUN #3
Device 1, Site 1	0	0	0
Device 1, Site 2	0	0	0
Device 1, Site 3	0	0	0
Device 2, Site 1	0	0	0
Device 2, Site 2	0	0	0
Device 2, Site 3	0	0	0
Device 3, Site 1	0	0	0
Device 3, Site 2	0	0	0
Device 3, Site 3	0	0	0
Positive Controls	+, +	+, +	+, +
Negative Control	0	0	0
Environmental Control	0	0	0

0 = No Growth
+ = Growth

TABLE 2. BI Test Results for the 5 minute, Gravity 132°C Half Cycles

IDENTIFICATION	RUN #1	RUN #2	RUN #3
Device 1, Site 1	0	0	0
Device 1, Site 2	0	0	0
Device 1, Site 3	0	0	0
Device 2, Site 1	0	0	0
Device 2, Site 2	0	0	0
Device 2, Site 3	0	0	0
Device 3, Site 1	0	0	0
Device 3, Site 2	0	0	0
Device 3, Site 3	0	0	0
Positive Controls	+, +	+, +	+, +
Negative Control	0	0	0
Environmental Control	0	0	0

0 = No Growth
+ = Growth

TABLE 3. Pre- and Post- Weight Results for the 2 minute, Prevacuum 132°C Half Cycles

RUN #	PRE-PROCESSING WEIGHT (g)	POST-PROCESSING WEIGHT (g)	% DIFFERENCE	MOISTURE LOCATION
1, Device 1	308.6	307.7	-0.29	No Moisture
1, Device 2	320.1	320.1	0.00	No Moisture
1, Device 3	333.3	333.5	0.060	No Moisture
2, Device 1	317.0	316.9	-0.03	No Moisture
2, Device 2	312.4	313.2	0.26	No Moisture
2, Device 3	330.4	330.4	0.00	No Moisture
3, Device 1	315.4	314.5	-0.29	No Moisture
3, Device 2	316.4	316.3	-0.03	No Moisture
3, Device 3	322.7	322.1	-0.19	No Moisture

TABLE 4. Pre- and Post- Weight Results for the 5 minute, Gravity 132°C Half Cycles

RUN #	PRE-PROCESSING WEIGHT (g)	POST-PROCESSING WEIGHT (g)	% DIFFERENCE	MOISTURE LOCATION
1, Device 1	317.8	315.7	-0.66	No Moisture
1, Device 2	310.2	308.7	-0.48	No Moisture
1, Device 3	333.3	331.7	-0.48	No Moisture
2, Device 1	315.3	314.0	-0.41	No Moisture
2, Device 2	318.4	317.5	-0.28	No Moisture
2, Device 3	323.1	322.0	-0.34	No Moisture
3, Device 1	299.9	300.2	0.10	No Moisture
3, Device 2	315.9	314.3	-0.51	No Moisture
3, Device 3	337.8	337.2	-0.18	No Moisture

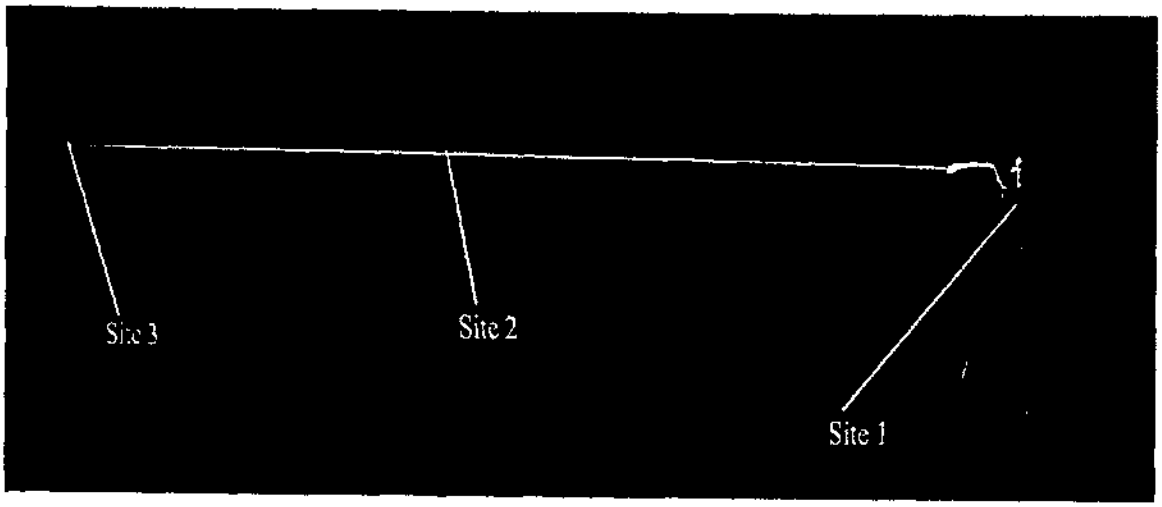

Figure 1. Inoculation Sites

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