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FINAL REPORT

CLEANING EVALUATION OF THE AIM "CLEAR FLUSH" LAPAROSCOPIC GRASPER

PROTOCOL NO. 200500607-02

LABORATORY NO. 281216

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)

CLEANING EVALUATION 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. 281216

STUDY DIRECTOR: _____ DATE: 18 Jun 2005

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QAU AUDIT STATEMENT

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

CLEANING EVALUATION OF THE AIM "CLEAR FLUSH" LAPAROSCOPIC GRASPER

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

Final Report Dated: 17 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 281216.

2. In accordance with the Good Laboratory Practice Regulations, the Sample Contamination 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: 14 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:

Emily Mitzel
Russell Lee
Steven Jensen
Sara Toole
Dr. Jerry Nelson
Jeff Hills
Nick Workman

QUALITY ASSURANCE: Brandy Giles DATE: 18 Jan 2005

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CLEANING EVALUATION OF THE AIM "CLEAR FLUSH" LAPAROSCOPIC GRASPER

LABORATORY NUMBER:	281216
PROTOCOL NUMBER:	200500607-02
SAMPLE SOURCE:	AIM Instruments
SAMPLE IDENTIFICATION:	AIM "Clear Flush" Laparoscopic Grasper
NUMBER OF SAMPLES:	4
DEVIATIONS:	None
DATA ARCHIVE LOCATION:	Sequentially by lab number
PROTOCOL APPROVAL DATE:	11 Jan 2005
SAMPLE RECEIVED DATE:	30 Dec 2004
LAB PHASE START DATE:	11 Jan 2005
LAB PHASE COMPLETION DATE:	14 Jan 2005
REPORT ISSUE DATE:	17 Jan 2005
TOTAL NUMBER OF PAGES:	9

INTRODUCTION:

This report describes the evaluation of the recommended cleaning procedures for BOSS "Clear Flush" Laparoscopic Grasper from BOSS Instruments. The devices were contaminated with blood soil (BLSO) containing *Geobacillus stearothermophilus*, ATCC #7953. Bioburden extractions were performed to determine the number of viable organisms present on one positive control device prior to cleaning. Three test devices were contaminated, cleaned, and an additional bioburden assay was performed on each device to determine the bioload reduction.

PROCEDURES:

Cleaning Procedure:

Culture Preparation: BLSO was inoculated with the test organism from a stock spore suspension maintained at 2-8°C. A standard plate count was performed on the inoculated BLSO to determine the initial titer of the test organism.

Sample Contamination: The devices were immersed in inoculated BLSO and allowed to remain in contact with the BLSO for 15 minutes. The soiled devices were placed into a clean pan, covered with a towel dampened with purified water (PURW), and allowed to sit for 30 minutes to simulate the wait time between contamination and cleaning. The instrument jaws and black rubber caps were open during contamination.

Positive Control Recovery: The positive control device was tested using the bioburden method described below. The extraction efficiency was determined by repeating the bioburden test procedure for a total of four consecutive extractions on the positive control.

Cleaning Procedure: In a clean metal pan, the enzymatic detergent Enzol™ was prepared according to the manufacturers recommendations. Fifty cc of the detergent were flushed through the flush port of each device. The flushes were repeated until the solution was clear.

The enzymatic detergent Enzol™ was prepared in an ultrasonic water bath according to the manufacturers recommendations. The devices were sonicated for ten minutes. The black lumen rubber seal and the jaw position were open during cleaning.

The devices were removed from the sonicator and placed into the metal pan that contained the enzymatic detergent. With a soft bristle brush, the devices were manually cleaned while immersed in the cleaning solution. Particular attention was given to crevices and other hard-to-clean areas.

The devices were thoroughly rinsed under lukewarm, running tap water for one minute. Fifty cc of tap water was flushed through the flush port of each device. The flushes were repeated until the water was clear.

The devices were dried with a clean, soft cloth. The flush ports were dried with compressed air until all the water was removed.

The devices were inspected for visible soil and found to be clean.

Bioburden Testing: The positive control and cleaned devices were tested for bioburden by immersing in peptone Tween® and shaking manually 100 times to extract the organisms present. Aliquots of the extract fluid were diluted where appropriate, and plated onto soybean casein digest agar (SCDA) or filtered through a 0.45 μm membrane and placed onto SCDA. Plates were incubated at 55-60°C for 24 ± 3 hours and colonies were enumerated.

Calculations: For the positive control, the percent efficiency was obtained by dividing the number of organisms recovered in the first extraction by the total number of organisms recovered from the product. The positive control titer and recovered counts from cleaned devices were corrected for the extraction efficiency.

The percent reduction in bacterial counts was calculated using the following formula:

$$\% \textit{ Reduction} = \frac{\textit{Initial Population} - \textit{Final Population}}{\textit{Initial Population}} \times 100\%$$

Where: Final population = Corrected number of organisms recovered from the cleaned devices
Initial population = Corrected positive control titer

Log reductions were calculated using this formula:

$$\textit{Log}\ \text{Reduction} = \textit{Log}\ \text{U} - \textit{Log}\ \text{C}$$

Where: U = Corrected positive control titer
C = Corrected number of organisms recovered from the cleaned devices

RESULTS:

The results of the cleaning evaluation are summarized in Table 1. Each device was inoculated and cleaned individually, and some variability is expected between devices. The BLSO and positive control titers are listed at the bottom of the table. The extraction efficiency and cleaning reduction values are based on a high inoculum to simulate worst case. Percentages may vary with samples contaminated at a lower level.

The cleaned devices were free of visible soil.

CONCLUSION:

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

Emily F. Mitzel, M.S. B.S.
Hospital Reprocessing Section Leader

Russell W. Lee, B.S.
Study Director

18 Jan 2005
Study Completion Date

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TABLE 1. Cleaning Results

DEVICE IDENTIFICATION	CORRECTED COUNTS PER UNIT	PERCENT REDUCTION	LOG_{10} REDUCTION
1	3.9×10^1	99.974%	3.6
2	9.2×10^1	99.937%	3.2
3	1.4×10^2	99.903%	3.0
Average	9.1×10^1	99.938%	3.3

BLSO Titer: 1.7×10^5 CFU/mL

Corrected Positive Control Titer: 1.0×10^5 CFU/device

Extraction Efficiency: 33.8%

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