



FINAL REPORT

CLEANING EVALUATION FOR THE FLUSHABLE RONGEURS

PROTOCOL NO. 200700209 REV 01

LABORATORY NO. 358861

PREPARED FOR:

AMERICAN MEDICAL PRODUCTS, INC. (AMP, INC.)

SUBMITTED BY:

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CLEANING EVALUATION FOR THE FLUSHABLE RONGEURS

LABORATORY NUMBER:	358861
PROTOCOL NUMBER:	200700209 REV 01
SAMPLE SOURCE:	American Medical Products, Inc. (AMP, Inc.)
SAMPLE IDENTIFICATION:	Flushable Rongeurs P.O. #010407
NUMBER OF TEST SAMPLES:	4
DEVIATIONS:	None
PROTOCOL APPROVAL DATE:	18 Jan 2007
SAMPLE RECEIVED DATE:	09 Jan 2007
LAB PHASE START DATE:	22 Jan 2007
LAB PHASE COMPLETION DATE:	24 Jan 2007
REPORT ISSUE DATE:	25 Jan 2007

INTRODUCTION:

This report describes the evaluation of the recommended cleaning procedures for the Flushable Rongeurs from American Medical Products, Inc. (AMP, Inc.). The devices were contaminated with defibrinated blood soil (DBLSO) containing *Geobacillus stearothermophilus*, ATCC #7953. Bioburden extractions were performed to determine the number of viable organisms present on one positive control device. Three test devices were cleaned and additional bioburden assays were performed to determine the bioload reduction of each device.

PROCEDURES:

Culture Preparation: The test soil was inoculated with the test organism from a stock spore suspension maintained at 2-8°C to yield a minimum population of 10⁴ CFU/mL. A standard plate count was performed on the inoculated test soil to determine the initial titer of the test organism.

Sample Contamination: Approximately 2 inches of the distal ends of the devices were immersed in the inoculated test soil. The remaining test soil was placed into a clean spray bottle, and the rest of the devices were sprayed with the test soil to achieve even coverage. The devices were simulated by opening and closing the jaws 10 times for each device. The devices were then allowed to remain in contact with the test soil for 15 minutes with the jaws open. The soiled devices were then placed into a clean pan, and the pan was covered with a towel dampened with purified water (PURW) and allowed to set for 30 minutes to simulate the wait time between contamination and cleaning.

Positive Control Recovery: The positive control device was tested using the bioburden method described below.



Cleaning Procedure: The enzymatic detergent, Enzo[®], was prepared following the manufacturer's recommendations using lukewarm tap water. Each device was fully immersed in the prepared detergent and allowed to soak for a minimum of 5 minutes with the jaws open. Each device was thoroughly cleaned with a soft bristle brush until all visible soil had been removed, paying particular attention to crevices and other difficult-to-clean areas of the device. Using the flush cannula supplied by the sponsor and ensuring that the cannula fit tightly into the flush port before flushing, the flush port on each device was flushed three times. Following cleaning, the devices were rinsed in lukewarm tap water for a minimum of one minute. The flush cannula was used to aid in rinsing each device three times each.

The enzymatic detergent, Enzo[®], was prepared following the manufacturer's recommendations using lukewarm tap water in an ultrasonic cleaning unit. The flush cannula and each device (with the jaws open) were fully immersed in the prepared detergent and allowed to sonicate for a minimum of 10 minutes. Following sonication, the devices were rinsed in lukewarm tap water for a minimum of one minute. The sonicated flush cannula was used to aid in rinsing the devices. The devices were dried using a clean soft cloth. Pressurized air was also used to aid in drying, specifically the flush port of the device.

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 the membrane was placed onto SCDA. Plates were incubated at 55-60°C for 24 \pm 3 hours and colonies were enumerated.

Calculations: The percent reduction after cleaning was calculated using the following formula:

$$\% \text{ reduction} = 100 - \left(\frac{\text{final population}}{\text{initial population}} \times 100 \right)$$

The log reduction after cleaning was calculated using the following formula:

$$\log \text{ reduction} = \log \text{ initial population} - \log \text{ final population}$$

Initial population = Positive control titer

Final population = Recovered counts of each device

RESULTS:

The results of the cleaning evaluation are summarized in Table 1. Each device was individually inoculated, and some variability is expected between devices. The DBLSO titer and the positive

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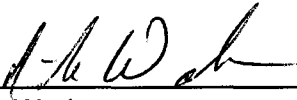
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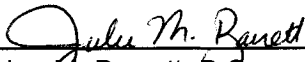
The cleaned devices were free of visible soil.

STATEMENT OF UNCERTAINTY:

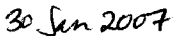
If applicable, the statement of uncertainty is available to sponsors upon request.



Nick Workman
Technical Reviewer



Julee M. Barrett, B.S.
Study Director



Study Completion Date

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TABLE 1. Cleaning Results

DEVICE IDENTIFICATION	COUNTS PER UNIT	PERCENT REDUCTION (%)	LOG ₁₀ REDUCTION
1	<1.0 x 10 ⁰	>99.99980	>5.7
2	<1.0 x 10 ⁰	>99.99980	>5.7
3	<1.0 x 10 ⁰	>99.99980	>5.7

DBLSO Titer: 1.4 x 10⁵ CFU/mL

Positive Control Titer: 5.1 x 10⁵ CFU/device



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