FINAL STUDY REPORT

STUDY TITLE:	**Steam Sterilization Efficacy Study - Reusable Devices - 132 °C Pre-vacuum Cycle**
PROTOCOL NUMBER:	RCA012114STM.01
PRODUCT:	SteriBest Instrument Tray (CP1038D2)
CLIENT:	RICA Surgical Products, Inc. 9207 Ivanhoe Street Schiller Park, IL 60716
PERFORMING LABORATORY:	**REDACTED**
RESULT SUMMARY:	**PASS**

1.0 PURPOSE / SCOPE

The purpose of this study was to demonstrate the efficacy of a 4-minute 132 °C pre-vacuum steam sterilization cycle specified by RICA Surgical Products, Inc. for sterilization of the SteriBest Instrument Tray (CP1038D2) in health care facilities.

2.0 CLIENT:

RICA Surgical Products, Inc.
9207 Ivanhoe Street
Schiller Park, IL 60716

3.0 TEST FACILITY:

REDACTED

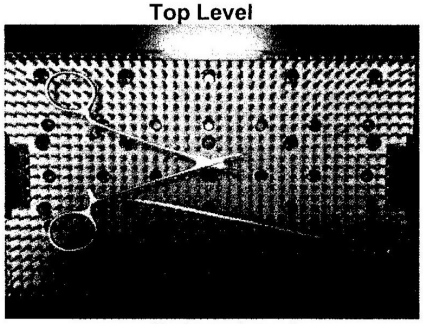
4.0 SCHEDULING

DATE SAMPLES RECEIVED:	January 06, 2014, January 20, 2014
PROTOCOL SIGNATURE COMPLETE:	February 07, 2014
STUDY INITIATION DATE:	February 14, 2014
STUDY COMPLETION DATE:	February 24, 2014

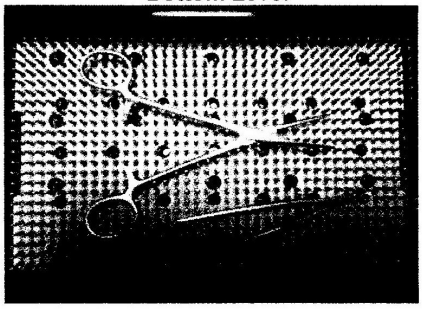
5.0 TEST ARTICLE IDENTIFICATION / TEST ARTICLE CHARACTERIZATION

The test article was the SteriBest Instrument Tray (CP1038D2). The device was packaged for sterilization by double wrapping in standard central supply wrap.

Top Level



Bottom Level



6.0 EXPERIMENTAL DESIGN

This sterilization efficacy study was based on the standard overkill method used for validation of steam sterilization cycles. The overkill method incorporates the equivalent of at least 10^6 bacterial spores with a D-value of at least 1.0 to demonstrate a 6-log reduction in a cycle that is one-half the dwell time of the specified cycle. A 6-log reduction in a half cycle extrapolates to a 12-log reduction in a full cycle, thereby providing a 10^{-6} sterility assurance level (SAL).

7.0 MATERIALS / EQUIPMENT

7.1 Testing

7.1.1 Lab materials and equipment were used as listed in the specified REDACTED Inc. Standard Operating Procedures (SOPs).

7.2 Processing

7.2.1 Packaging materials for steam sterilization were provided by REDACTED

7.2.1.1 Cardinal Health Convertors Bio-Shield Regular Sterilization Wrap, 40" x 40", REF 4040

7.2.1.2 Propper STRATE-LINE® Autoclave Indicator Tape, ¾ in x 60 yd, Reorder Number 268005

7.2.2 The steam sterilization half cycles were conducted at REDACTED in a steam autoclave that is operated and calibrated following REDACTED SOPs.

7.2.2.1 Steris LAB250, Serial # 0332809-19, Calibrated 02-26-13

Note: A Steris LAB 250 steam sterilizer was used for the half cycle runs. The Steris LAB 250 sterilizer series are Century Steam Sterilizers modified to serve the life sciences industry. The Steris LAB 250 sterilizer provides the same time-proven, safe, reliable chamber and stand assembly as the Steris Century Steam Sterilizer offered to the healthcare and life sciences markets, while allowing more flexibility in cycle control.

7.2.3 Microbial challenge devices were provided by REDACTED

7.2.3.1 *Geobacillus stearothermophilus* BI thread, ATCC 7953, MESA Labs, Lot Number: 3Y61074, Exp. Date: 05/2014; Lot Number: 3Y61075, Exp. Date: 08/2014.

8.0 PROCEDURE

8.1 PRODUCT INOCULATION

8.1.1 The devices were autoclaved prior to inoculation using a standard decontamination cycle.

8.1.2 Four (4) devices per half cycle were each inoculated with a *Geobacillus stearothermophilus* bioindicator, resulting in a confirmed population of 10^6 spores per bioindicator, with a D-value of 1.8 minutes, as shown in Table 1. Refer to Attachment A for the population confirmation reports and the manufacturer certificate of analysis.

Table 1: Inoculation Information

Organism	ATCC #	Half Cycle	Lot #	Population Confirmation	D-value
Geobacillus stearothermophilus	7953	1	3Y61074	3.8×10^6	1.8 minutes
		2	3Y61075	1.3×10^6	
		3			

8.1.3 The location of the BIs were:

8.1.3.1 Top Level

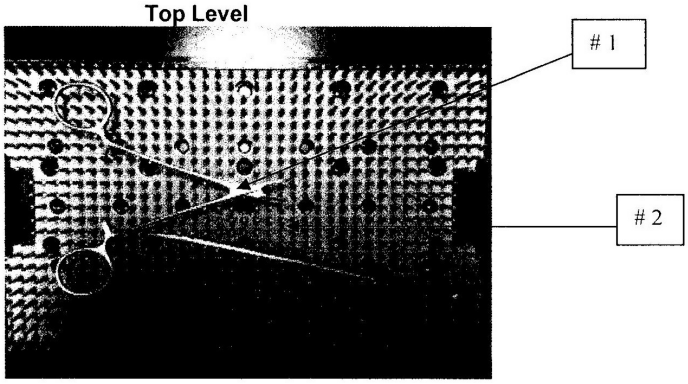
1. Small Forceps – mated area of hinge
2. Underneath blue rubber mat

8.1.3.2 Bottom Level

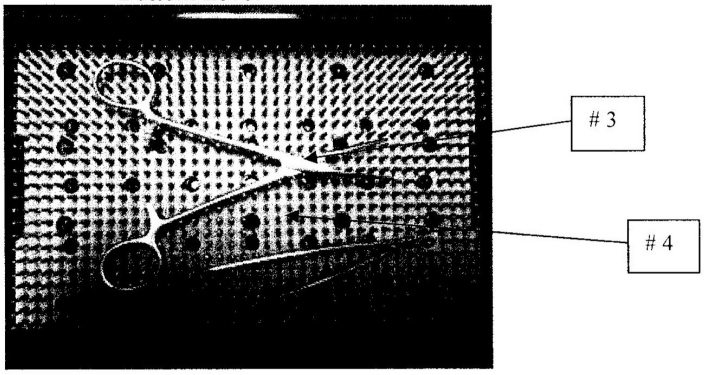
3. Large Forceps – between rigid area of grasping arms
4. Underneath blue rubber mat

These areas were considered to be the most challenging, accessible locations on the within the kit to sterilize.

Top Level



Bottom Level



8.1.4 One (1) inoculated bioindicator for each half cycle was used as the positive control and was handled in the same manner as the test samples, but did not undergo the sterilization process.

8.1.5 After inoculation, each device was placed into the tray and the tray was packaged for sterilization by double wrapping in standard central supply wrap.

8.2 HALF CYCLES

8.2.1 The number of inoculated bioindicators processed per half cycle was four (4).

8.2.2 The half cycle of 2 minutes was initiated when the autoclave reached 132 °C. The temperature during the half cycle was within + 3 °C.

8.2.3 Upon completion of the cycle, the devices were removed from the autoclave and transported to the lab for testing.

8.2.4 Steps 8.2.1 through 8.2.3 were repeated two more times for a total of three half cycle runs, as shown in Table 2.

Table 2: Half Cycle Data

Parameter	Half Cycle 1	Half Cycle 2	Half Cycle 3
Temperature	132.0 – 133.9 °C	132.0 – 133.8 °C	132.0 – 133.8 °C
Dwell time	2 minutes	2 minutes	2 minutes
Status of cycle	Acceptable	Acceptable	Acceptable

8.3 STERILITY TESTING

8.3.1 The four (4) bioindicators and one (1) positive control(s) from each of the three (3) half cycles were individually tested for sterility according to [REDACTED] Standard Operating Procedure MA228SOP. The [REDACTED] Client Technical Procedure (CTP) for performing the sterility test is included as Attachment B.

8.3.2 Each bioindicator was tested by direct immersion in Soybean-Casein Digest Broth (SCD) and incubated at 55 – 60 °C for 7 days. Test samples were checked for growth according to the established schedule.

8.3.3 Sterility test results were recorded for each sample and for each half cycle as positive or negative for *G. stearothermophilus*, as shown in Table 3.

Table 3: Sterility Test Results

Sample	Half Cycle 1	Half Cycle 2	Half Cycle 3
Test Samples	4 Negative	4 Negative	4 Negative
Positive Controls	1 Positive	1 Positive	1 Positive

9.0 RESULTS

This half-cycle study was successful in producing no growth in the inoculated challenge products in all three cycles. All acceptance criteria as specified in Section 12.0 of the protocol were met during the course of this study, as shown in Table 4.

Table 4: Acceptance Data

Acceptance criteria	Half Cycle 1	Half Cycle 2	Half Cycle 3
Inoculum confirmation of 10^6 CFU	Criteria met	Criteria met	Criteria met
Sterility test samples negative	Criteria met	Criteria met	Criteria met
Positive control(s) positive	Criteria met	Criteria met	Criteria met
Half cycle within specifications	Criteria met	Criteria met	Criteria met

Reference Attachments C, D, and E for reports on Cycles 1, 2, and 3, respectively.

10.0 CONCLUSION

The results shown in Section 9.0 provide evidence that RICA Surgical Products, Inc.'s SteriBest Instrument Tray (CP1038D2) can be steam sterilized to a sterility assurance level (SAL) of at least 10^{-6} using the following cycle:

Pre-Vacuum Steam Sterilization – Full-Cycle:
Sterilization temperature – 132 °C
Sterilization exposure time – 4 minutes

11.0 LIST OF ATTACHMENTS

Attachment A Population Confirmation Report & Manufacturer Certificate of Analysis.
Attachment B [REDACTED] CTP for the sterility test
Attachment C Half Cycle 1 report
Attachment D Half Cycle 2 report
Attachment E Half Cycle 3 report

12.0 AMENDMENTS / DEVIATIONS

No amendments or deviations from the protocol were encountered during this study.

13.0 RECORD RETENTION

An official copy of all documents associated with this study and the raw data pertinent to the study will be retained according to [REDACTED] standard operating procedures for archival.

14.0 INFORMATIVE REFERENCES

14.1 AAMI TIR 12: 2010, *Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A Guide for Device Manufacturers* (AAMI TIR 12)

14.2 ANSI / AAMI ST 79: 2010, *Comprehensive guide to steam sterilization and sterility assurance in health care facilities* (AAMI ST 79)

14.3 ISO 17665-1: 2006, *Sterilization of health care products -- Moist heat -- Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices* (ISO 17665-1: 2006)

14.4 AAMI TIR 39: 2009, *Guidance on selecting a microbial challenge and inoculation sites for sterilization validation of medical devices*

14.5 USP / NF, U.S. Pharmacopia, current version (USP)

14.6 [REDACTED], MA228SOP, "*Sterility Testing- Reuse Studies*", current version

14.7 [REDACTED], MA229SOP, "*Product Inoculation*", current version

14.8 REDACTED MP408SOP, "*AMSCO Lab 250 Sterilization Operation*", current version

15.0 COMPLIANCE

The study was performed in accordance with applicable Good Manufacturing Practices.

16.0 TEST ARTICLE DISPOSITION

All test articles will be decontaminated and returned to the client unless otherwise requested by the Client.

17.0 APPROVAL / SIGNATURES

CLIENT:

NAME: _____ TITLE: _____
(please print)

SIGNATURE: _____ DATE: _____

REDACTED

NAME: Shelley Green TITLE: Manager of Specialized Studies

SIGNATURE: Shelley Green DATE: 02-26-14

NAME: Hailey Richards TITLE: Specialized Studies Project Manager

SIGNATURE: Hailey Richards DATE: 02-26-14

14.8 REDACTED MP408SOP, "*AMSCO Lab 250 Sterilization Operation*", current version

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17.0 APPROVAL / SIGNATURES

CLIENT:

NAME: Laura Haak (please print) TITLE: QA Manager

SIGNATURE: [signature] DATE: 2/28/2014

REDACTED

NAME: Shelley Green TITLE: Manager of Specialized Studies

SIGNATURE: [signature] DATE: 02-26-14

NAME: Hailey Richards TITLE: Specialized Studies Project Manager

SIGNATURE: [signature] DATE: 02-26-14